

SAP White Paper



COMPLYING WITH U.S. FDA TITLE 21 CFR PART 11 FOR THE LIFE SCIENCES INDUSTRY

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EXECUTIVE SUMMARY

SAP has enjoyed over 30 years of partnership with the life sciences industry. Currently, there are close to 1,500 installations of mySAP™ ERP software among pharmaceutical, medical diagnostics and devices, and biotechnology companies worldwide. Although the infrastructure and solutions provided by each of these installations are different, they have a common key business requirement: regulatory compliance. Given that almost all of these life sciences companies want to compete in the lucrative United States market, they all must then comply with U.S. FDA regulations – including those requirements that regulate the use of computerized systems that support good clinical, laboratory, and manufacturing practice (also known as predicate rules or GxPs). Another regulation, 21 CFR Part 11 Electronic Records; Electronic Signature; Final Rule, signaled FDA’s awareness of the transition from paper-based, manual systems to computerized systems occurring within the life sciences industry.

Applying these requirements to the numerous computerized systems within life sciences companies translates into millions of dollars in project costs to validate these systems and significant annual costs to maintain them in a “validated state” for their productive lifetime.

A COMPLIANCE MODEL IN TRANSITION

FDA’s systems-based inspection approach that was officially adopted in February 2002 initiated a transition of how companies must now assess compliance from a systems-oriented approach rather than isolated functional units (see Table 1).

CURRENT STATE	FUTURE STATE
Isolated functional units	Integrated systems-oriented approach to compliance
Focus on remediation of 483’s and Warning Letters exclusively	Enforced compliance built into each quality system
Fragmented compliance systems (hybrid systems)	Integrated compliance systems
Validation and maintenance of numerous stand-alone systems	Validation and maintenance of a consolidated infrastructure
Batches on hold, delayed investigations, and lengthy reviews	Real-time investigations
Inability to identify process improvements	Electronic batch records Real-time batch record review Enterprise-wide visibility of compliance activities

Table 1: FDA’s Systems-Based Inspection Approach

The systems-based inspection approach also recognizes the widespread use of computerized systems to support each company’s quality system. Therefore, the validation and security of these systems are being much more closely reviewed during an inspection.

COST OF COMPLIANCE

Figures 1 and 2 illustrate the cost of compliance and non-compliance.

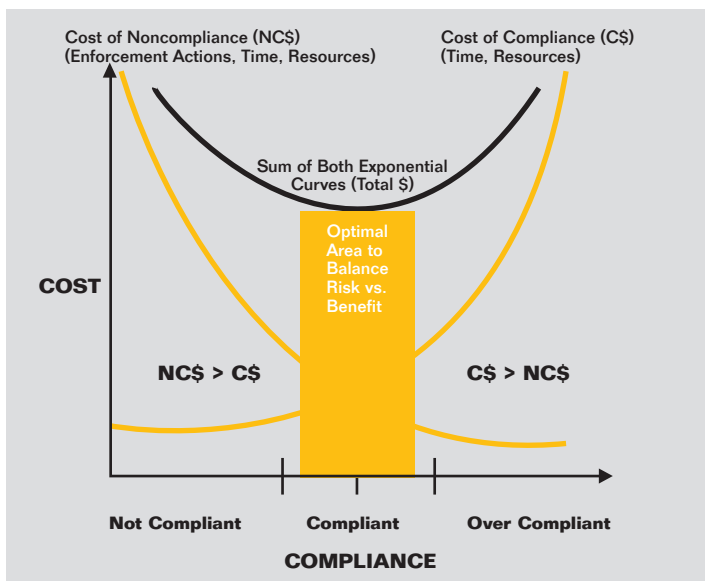


Figure 1: Compliance Cost Model

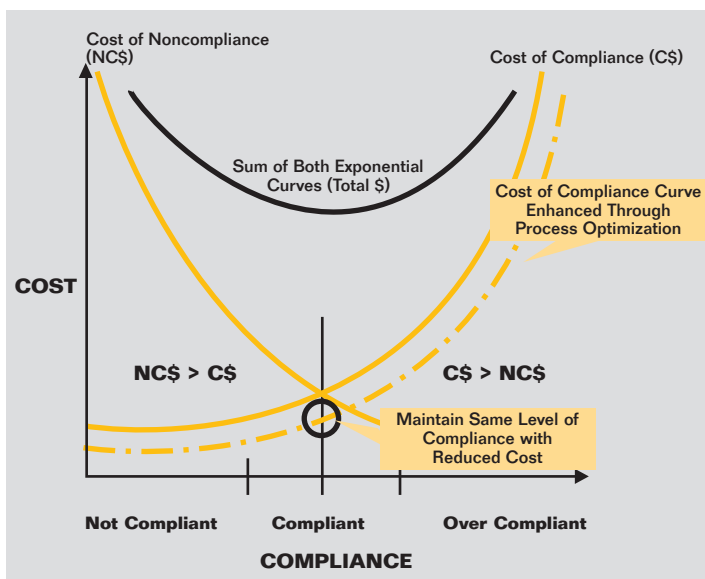


Figure 2: Compliance Cost Model Reduced Through Process Optimization

Figure 1 and Figure 2:

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Figure 1 represents two opposing exponential curves depicting the cost of noncompliance and compliance. The cost of noncompliance is determined to be a function of FDA's enforcement actions including Warning Letters, import detention, and consent decree, and the time and resources required to remediate FDA's observations. The cost of compliance is determined to be a function of time and resources. It is also illustrated by the graph that the state of compliance is not dichotomous. Rather, compliance is a state of operation determined by each company's interpretation of pertinent FDA regulations and their corporate culture applied to the various business processes within the quality system. The three levels of compliance are therefore subjective as depicted by the range for each level.

Figure 2 illustrates the beneficial movement of the cost of compliance curve manifested by process optimization and other internal cost reductions including consolidation of IT systems. Therefore, companies can maintain or improve their level of compliance for significantly reduced costs.

A "WIN-WIN" PROPOSITION FOR LIFE SCIENCES

Various life sciences companies have taken advantage of this "win-win" proposition and leveraged their mySAP ERP infrastructure to include the following components:

- Enterprise asset management
- Enterprise quality management
 - Supplier quality management
 - Laboratory information system (LIMS)
 - Problem reporting/corrective action preventative action (CAPA) execution
- Manufacturing execution/electronic batch record
- Qualifications management (training)
- Warehouse management

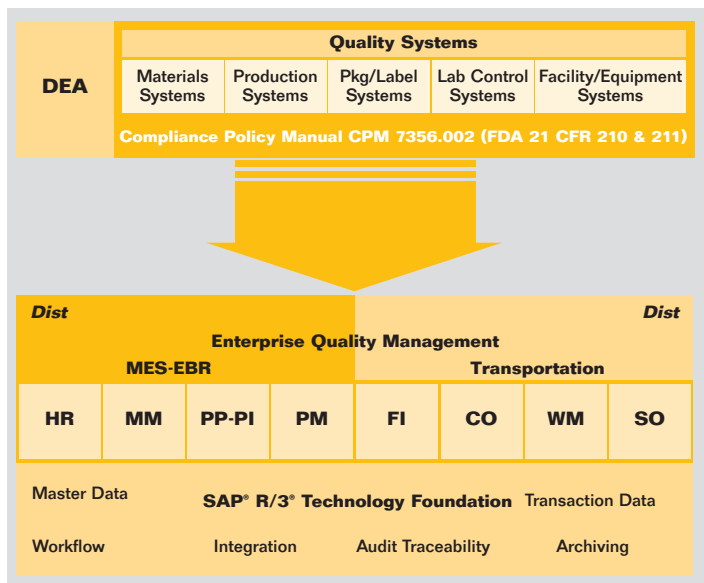


Figure 3: Life Sciences Compliance Model in Transition

These pharmaceutical, medical diagnostics and devices, and biotechnology companies have promoted FDA compliance while reducing their costs and maximizing their return on investment (ROI).

INTRODUCTION

The purpose of this document is to describe the functions and features of mySAP ERP that (in the opinion of SAP AG) demonstrate technical compliance with U.S. FDA 21 CFR Part 11 Electronic Records; Electronic Signatures; Final Rule and several international good manufacturing practice (GMP) guidelines having similar requirements. This document provides background information about the regulation, discusses how mySAP ERP complies with this rule, and provides examples of electronic records and signatures within mySAP ERP. Prior releases can be compliant depending on the scope of functions implemented. In other instances, Part 11 compliance can still be achieved with some customization and organizational measures.

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

The U.S. Food and Drug Administration (FDA) is a public health agency that is charged with protecting American consumers by enforcing the U.S. Federal Food, Drug, and Cosmetic Act and other related public health laws. FDA regulates over U.S. \$1 trillion worth of products, which account for 25 cents of every dollar spent annually within the United States. These products include:

- Food for human and animal consumption
- Pharmaceuticals consisting of ethical, generic, and over-the-counter (OTC) drugs for human use as well as medicines for animals
- Biological and related products including blood, vaccines, and biological therapeutics
- Medical devices
- Radiation-emitting devices such as microwaves
- Cosmetics

FDA monitors the manufacture, import, transport, storage, and sale of these products by some 98,000 FDA-regulated businesses in the United States alone and several thousand international organizations that conduct business in the U.S.

Compliance with FDA regulations is a market requirement. In addition, products require FDA approval before they can be marketed or sold in the United States. Noncompliance with any of the laws enforced by FDA can be very costly in the form of recalls and legal sanctions such as import detentions. When warranted, FDA seeks criminal penalties, including prison sentences, against manufacturers and distributors.

21 CFR PART 11 ELECTRONIC RECORDS; ELECTRONIC SIGNATURES; FINAL RULE

The U.S. FDA regulation **21 CFR Part 11 Electronic Records; Electronic Signatures; Final Rule** (which we will refer to simply as Part 11) was the result of a six-year effort by FDA (with input from industry) to supply all FDA-regulated companies with requirements on how paperless (that is, electronic) record systems could be maintained while still complying with good clinical, laboratory, and manufacturing practices (GxP), including:

- GMP: 21 CFR 110 (Food), 210 (Drugs in general, also includes GMP for Biologics), 211 (Finished Pharmaceuticals), 820 (Medical Device)
- GLP 58
- GCP (50, 54, 56)
- EU 178/2002 regulation: general food law (effective January 2005)

The regulation also details very specific requirements for electronic and digital signatures because FDA considers these signatures to be legally binding.

Since its publication more than six years ago, this regulation has been subject to evolving interpretations both by FDA and industry.

In February 2003, FDA withdrew all Part 11 guidelines and the Compliance Policy Guide. Reasons for the withdrawal of all Part 11 guidelines and Compliance Policy Guide in February 2003 by FDA were stated as such by FDA, *Guidance for Industry Part 11, Electronic Records; Electronic Signatures – Scope and Application* in August 2003:

“Concerns have been raised that some interpretations of the Part 11 requirements would unnecessarily restrict the use of electronic technology in a manner that is inconsistent with FDA’s stated intent in issuing the rule . . . Significantly increase the costs of compliance to an extent that was not contemplated at the time the rule was drafted . . . Discourage innovation and technological advances without providing a significant public health benefit. These concerns have been raised particularly in the areas of Part 11 requirements for validation, audit trails, record retention, record copying, and legacy systems.”

PHARMACEUTICAL cGMPs FOR THE TWENTY-FIRST CENTURY: A RISK-BASED APPROACH

In August 2002, FDA announced a significant initiative to enhance the regulation of pharmaceutical manufacturing and product quality: by applying a scientific and risk-based approach to product-quality regulation incorporating an integrated quality-systems approach to current good manufacturing practice (cGMP). FDA has been developing a more systematic and rigorous risk-based approach toward compliance and using good science. A justifiable and documented risk assessment, and one that is defensible, has become a predominant theme within FDA’s recent initiatives.

NEW PART 11 GUIDANCE

In August 2003, FDA published the final guidance entitled *Guidance for Industry Part 11, Electronic Records; Electronic Signatures – Scope and Application*.

The final guidance delineates how FDA intends to reexamine Part 11 and may propose revisions to that regulation. The approach outlined in the guidance is based upon the following:

- FDA intends to narrowly interpret the scope of Part 11 in an effort to clarify fewer records to be considered subject to Part 11.
- FDA intends to exercise enforcement discretion with respect to certain Part 11 requirements for both legacy and current systems.
- Predicate rule requirements for records subject to Part 11 will be enforced.
- Hybrid systems necessary to comply with Part 11 requirements are acceptable.

What has not changed? FDA's interpretation of the following requirements has not changed:

- Controls for closed systems
- Controls for open systems
- Electronic signatures

Ultimately, companies must comply with applicable predicate rules. Records that are required to be maintained or submitted must remain secure and reliable in accordance with the predicate rules.

DISCUSSION OF 21 CFR PART 11 RULE

SUBPART A – GENERAL PROVISIONS

What mySAP ERP Functionality May Be Regulated?

FDA regulations encompass many mySAP ERP functions. The only functional areas that may be completely excluded from the FDA scope are finance (for example, the financial accounting, controlling, and asset management components) and planning (for example, the demand management, forecasting, profitability analysis, and sales and operations planning components).

All other functional areas and components that are FDA GxP-relevant must comply with Part 11 based upon the predicate rules:

- Logistics:
 - Materials Management (MM)
 - Plant Maintenance (PM)
 - Production Planning (PP)
 - Production Planning Process Industries (PP-PI)
 - Quality Management (QM)
 - Sales and Distribution (SD)
 - Logistics Execution (LE)
 - Environment, Health & Safety (EH&S)
 - Central functions:
 - Batch management
 - Handling unit management
 - Document management
- Cross-application components
 - Engineering Change Management
 - Logging (audit trail reporting)

For additional information, Appendices 1 and 2 contain the SAP/FDA cGMP functionality matrix for both pharmaceuticals and medical devices. These matrices illustrate how mySAP ERP promotes compliance to these regulations and provides guidance as to what functionality (and electronic records) may be regulated by FDA.

SUBPART B – ELECTRONIC RECORDS

FDA defines an electronic record as “any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system.”

Applying this comprehensive definition to mySAP ERP, there are various types of electronic records, such as:

- Configuration within the implementation guide
- Transports and business configuration sets used to migrate configuration from one system to another
- Master data such as the material master, vendor, resource, recipe, and customer
- Business processing objects such as purchase orders, process orders, and inspection lots
- Business process or transaction execution electronic records such as material documents
- Electronic or digital signatures

Other electronic record types maintain change and deletion (that is, audit trail) information for the mySAP ERP objects mentioned above. These include:

- Change master record (Engineering Change Management component)
- Change document objects
- Table logging

Change Master Record

A change master record captures the changes made to master data through the mySAP ERP Engineering Change Management (ECM) component. Figure 4 illustrates the master data or object types that can be managed using Engineering Change Management.

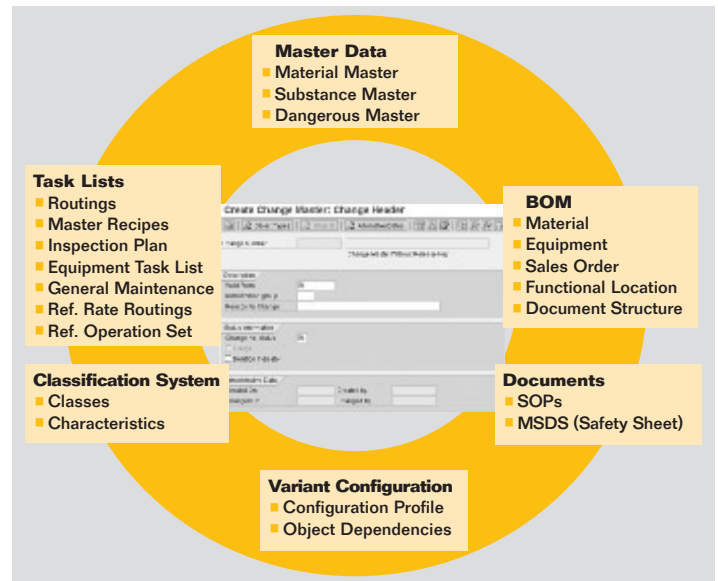


Figure 4: Linked Object Types in Engineering Change Management

Change master records provide a full audit trail or change history of the master data, including the reason for change. Some people incorrectly associate this requirement with Part 11 when indeed, as discussed in comment 74 of the preamble, “The agency does not believe that Part 11 needs to require recording the reason for record changes because such a requirement, when needed, is already in place in existing regulations that pertain to the records themselves.” An example is §211.194 (b), “Complete records shall be maintained of any modification of an established method employed in testing. Such records shall include the reason for the modification . . .”

Change Document Object

A change document object captures changes to fields within a transaction and writes this information to a unique record. This record is date and time stamped and maintains the old and new values for each of the fields that have been changed in addition to the user ID of the person who made the change. A report is run to query and display the audit trail record. These objects may be active in the shipped version of SAP software or may require configuration for activation. Figure 5 illustrates a change document object record for a resource substitution within a master recipe.



Figure 5: Example Change Document Object for Master Recipe Change

For further information, refer to the manual *E-Records* in SAP Help Portal.

Table Logging

Where change masters or change document objects do not exist, an alternative method for maintaining an audit trail is required. Activating the log data changes the flag in the technical settings of the table, captures all the changes made to a specific table, and writes this information into a unique record maintained within the DBTABLOG table. Any transaction within mySAP ERP consists of multiple tables where the data is recorded and maintained. Therefore, to view the complete audit trail, a report is run to query and display each record associated with a specific event. The report provides all the required information for the audit trail, including system date and time stamps and the old and new values for each of the fields that have been changed within each table. The report can also provide the full printed name of the user instead of the user ID. Figure 6 illustrates the table log record.

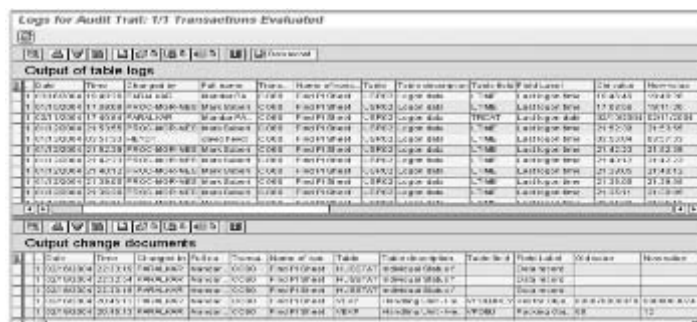


Figure 6: Output of Table Log and Change Document Log

Table logging may affect system performance depending on the number of records that are generated. However, table logging is only required in some instances. System configuration should be reviewed when table logging requirements have been identified.

Date and Time Stamp

mySAP ERP uses the application server time for change master record, change document objects, and table logging activities. Application server time is unique and unequivocal.

For customers with multiple time zones, procedures must be in place to define the time zone of the application server and describe how the date and time stamp is to be interpreted by each site. In addition, the procedures should include daylight savings time requirements. These procedures should be included in performance qualification testing.

Electronic Copies for Inspection

Consequent to FDA's systems-based inspection approach, mySAP ERP has become more involved in FDA inspections as it is routinely used to support the quality system and all other subsystems. Reports and electronic records can be printed or exported into several industry-standard formats such as Adobe PDF and Extensible Markup Language (XML).

Retention and Maintenance of Electronic Records

All electronic records can be maintained in the active database or archived to accommodate all required retention periods even when software is upgraded. Access to these records is secured using standard SAP authorization profiles. In addition, mySAP ERP maintains the link between electronic signatures executed to electronic records even after archiving.

Hybrid Systems

As discussed in the new FDA Part 11 guidance, hybrid systems necessary to comply with Part 11 requirements are acceptable. Information that has been recorded in SAP software or activities that have been performed directly in SAP software can be printed or exported into several industry-standard formats such as Adobe PDF and XML. An example of an SAP hybrid system is a batch record that includes printouts of process instruction (PI) sheets that have been executed by operators and quality personnel.

Another hybrid system with a different twist is part of a customer's corrective action preventative action (CAPA) program using the Quality Notification component as the CAPA solution. Paper documents with handwritten approvals including engineering and laboratory reports are scanned into the Content Server component and attached to investigations within the mySAP ERP system. Thus, an investigation within mySAP ERP contains electronic records, including electronic signatures, executed as part of the life cycle of the investigation and electronic images of documents that contain handwritten approvals.

All hybrid systems require procedural controls to maintain compliance and need to be included in the scope of each customer's computerized system validation.

SUBPART C – ELECTRONIC SIGNATURE

Part 11 provides requirements under which FDA will consider electronic records equivalent to paper records and electronic signatures equivalent to traditional handwritten signatures. Part 11 does not delineate where electronic records and electronic signatures are required. Instead, FDA specifies that these requirements are defined by the “predicate rule” such as current good manufacturing practice for finished pharmaceuticals (21 CFR Part 211) and medical devices (21 CFR Part 820). Using these two regulations as examples, the following list delineates some examples where cGMP explicitly defines requirements for signatures. It is important to note that various other passages implicitly call for signatures as in the case wherever the words “approved, signed, initialed, or verified” are used (for example, §211.100).

§ 211.100 Written procedures; deviations – (a) *These written procedures including . . . shall be drafted, reviewed and approved by the appropriate organizational units and reviewed and approved by the quality control unit.*

§ 211.182 Equipment cleaning and use log – *The persons performing and double-checking the cleaning and maintenance shall date and sign or initial the log indicating that the work was performed.*

§ 211.186 Master production and control records – (a) *To assure uniformity from batch to batch, master production and control records for each drug product, including each batch size thereof, shall be prepared, dated, and signed (full signature, handwritten) by one person and independently checked, dated, and signed by a second person.*

(b)(8) *Master production and control records shall include: . . . A description of the drug product containers, closures, and packaging materials including a specimen or copy of each label and all other labeling signed and dated by the persons responsible for approval of such labeling.*

§ 211.188 Batch production and control records — (a) An accurate reproduction of the appropriate master production or control record, checked for accuracy, dated, and signed.

§ 211.192 Production record review — All drug product production and control records, including those for packaging and labeling, shall be reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed.

§ 211.194 Laboratory records — (a)(7) The initials or signature of the person who performs each test and the date(s) the tests were performed.

(a)(8) The initials or signature of a second person showing that the original records have been reviewed for accuracy, completeness, and compliance with established standards.

§ 820.30 Design controls — (c) The design input requirements shall be documented and shall be reviewed and approved by a designated individual(s). The approval, including the date and signature of the individual(s) approving the requirements, shall be documented.

(d) Design output shall be documented, reviewed, and approved before release. The approval, including the date and signature of the individual(s) approving the output, shall be documented.

§ 820.40 Document controls — (a) Document approval and distribution. Each manufacturer shall designate an individual(s) to review for adequacy and approve prior to issuance all documents established to meet the requirements of this part. The approval, including the date and signature of the individual(s) approving the document, shall be documented.

(b) Changes to documents shall be reviewed and approved by an individual(s) in the same function or organization that performed the original review and approval, unless specifically designated otherwise . . . Change records shall include a description of the change, identification of the affected documents, the signature of the approving individual(s), the approval date, and when the change becomes effective.

§ 820.75 Process validation — (a) The validation activities and results, including the date and signature of the individual(s) approving the validation and where appropriate the major equipment validated, shall be documented.

§ 820.80 Receiving, in-process, and finished device acceptance — (d) Finished devices shall not be released for distribution until: (1) The activities required by the DMR are completed; (2) the associated data and documentation are reviewed; (3) the release is authorized by the signature of a designated individual(s); and (4) the authorization is dated.

(e) Each manufacturer shall document acceptance activities required by this part. These activities include: (1) The acceptance activities performed; (2) the dates acceptance activities are performed; (3) the results; (4) the signature of the individual(s) conducting the acceptance activities; and (5) where appropriate the equipment used.

§ 820.90 Nonconforming product — (b) Disposition of the nonconforming product shall be documented. Documentation shall include the justification for use of nonconforming product and the signature of the individual(s) authorizing the use.

§ 820.120 Device labeling — (b) Labeling shall not be released for storage or use until a designated individual(s) has examined the labeling for accuracy including, where applicable, the correct expiration date, control number, storage instructions, handling instructions, and any additional processing instructions. The release, including the date and signature of the individual(s) performing the examination, shall be documented in the DHR.

Note — Additional customer approval or signature requirements may be defined by their internal procedures in support of cGMP, such as approvals for approved suppliers and for new or changed user access authorization.

Electronic and Digital Signatures in mySAP ERP

ELECTRONIC AND DIGITAL SIGNATURE DEFINITION ACCORDING TO 21 CFR PART 11

The following are definitions as written in 21 CFR Part 11:

- **Electronic signature** – Electronic signature means a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent to the individual's handwritten signature.
- **Digital signature** – Digital signature means an electronic signature based upon cryptographic methods of originator authentication, computed by using a set of rules and a set of parameters such that the identity of the signer and the integrity of the data can be verified.
- **Closed system** – Closed system means an environment in which system access is controlled by persons who are responsible for the content of electronic records that are on the system.
- **Open system** – Open system means an environment in which system access is not controlled by persons who are responsible for the content of electronic records that are on the system.

SAP DIGITAL SIGNATURE

Throughout the mySAP ERP solution, the term “digital signature” is referenced in each dialog screen during signature execution and electronic record reporting. The term “electronic signature” is not referenced within mySAP ERP. This is based upon SAP’s interpretation of the Part 11 signature definitions concerning the use of cryptographic encryption techniques like PKCS#7. All signatures executed within mySAP ERP utilize cryptographic encryption techniques. Therefore, SAP defines all signatures within mySAP ERP to be digital signatures even when the mySAP ERP system is determined to be a closed system.

This mechanism is based on Secure Store and Forward (SSF) mechanisms and requires an external security product (see the SAP Complementary Software Program; interface BC-SSF) and an installed public-key infrastructure (PKI). Every signer is referenced using the SSF profile signature types in mySAP ERP.

To ensure the integrity of signatures within an electronic system and protect against falsification and data corruption, FDA is clear that the system must actively detect and prevent unauthorized access including reporting these attempts to the system security unit. Indeed, in comment 133 of the preamble, FDA equates the significance to reporting and response of unauthorized access with how “individuals would respond to a fire alarm.” To satisfy the requirements defined in §11.300(d), mySAP ERP provides the following safeguards:

- When the number of failed attempts (for either logon or signature) is exceeded, mySAP ERP prevents the user from further access without intervention from the security administration. Note: the number of failed attempts allowed is configurable.
- mySAP ERP generates an express mail within SAPOffice and sends it to a defined distribution list to notify the security administration “in an immediate and urgent manner.” In addition, any Messaging Application Programming Interface (MAPI)-compliant messaging system can be interfaced to mySAP ERP to send this message externally to e-mail systems such as Microsoft Exchange or even a paging system.
- An electronic record of all failed attempts (for either logon or signature) is maintained in the Security Audit Log. mySAP ERP also generates electronic records for the locking and unlocking of users.

System signature with authorization by user ID and password is available from the following SAP R/3® release:

- First shipment with release 4.6C
- Usage of PKCS#7 standard, encryption executed by 128 bit
- No external security product is necessary. When logging on to system, users identify themselves by entering their user IDs and passwords. The SAP system then executes the digital signature. The user name and ID are part of the signed document. Public key infrastructure can be administered by the customers themselves, which is sufficient according Part 11 for digital signature.

Digital user signature with verification is available from the following SAP R/3 release:

- First shipment with release 4.0B (1998)
- External security (third-party) product necessary. Users execute digital signatures themselves using their private keys. The executed signatures are automatically verified.
- Refer to SAP Service Marketplace > alias “Security” > Security Partners
<http://www.sap.com/partners/marketplace/>
- Crypto hardware and biometrics, such as smart card and fingerprint, must support the PKCS#7 standard data format. This mechanism is based on Secure Store and Forward mechanism (interface BC-SSF).

Electronic and digital signatures in mySAP ERP satisfy all applicable Part 11 requirements (please refer to the summary table in the following section entitled “How Does mySAP ERP Comply with Part 11?”).

Electronic signatures are already implemented in mySAP ERP for the following business processes and components:

- PP-PI: Process step completion within process instruction sheets and acceptance of process values outside predefined tolerance limits (CO60)
- PP-PI: Soft logon PI-sheet service user can only display PI-sheet and dialog user is required to login and work on PI-sheet (CO60)
- ECM: Engineering Change Management: Status change of Engineering Change Order: Change Number: create and change (CC01, CC02)
- ECM: Engineering Change Management: Status Change of Object Management Records (CC22). Conversion of a change request to a change order in engineering change management
- EBR: Electronic batch record approval (COEBR)
- QM: Inspection lot: results recording (QE01, QE02, QE51N)
- QM: Usage decision (quality disposition): Record and change (QA11, QA12)
- QM: Physical Sample Drawing (QPR1, QPR2)

- DMS: Document Management Status create/change (CV01N, CV02N)
- cProject: for example, document approval, project activities status change approval, and checklist/stage gate approval
- Where multiple signatures may be required, mySAP ERP provides signature strategies that define allowed signatures and the sequence in which they must be executed. Specifically for quality management results recording and usage decision, user statuses can be configured to require multiple signatures.

Figure 7 illustrates the execution of a signature in mySAP ERP; Figure 8 is an example of the electronic record of a signature.

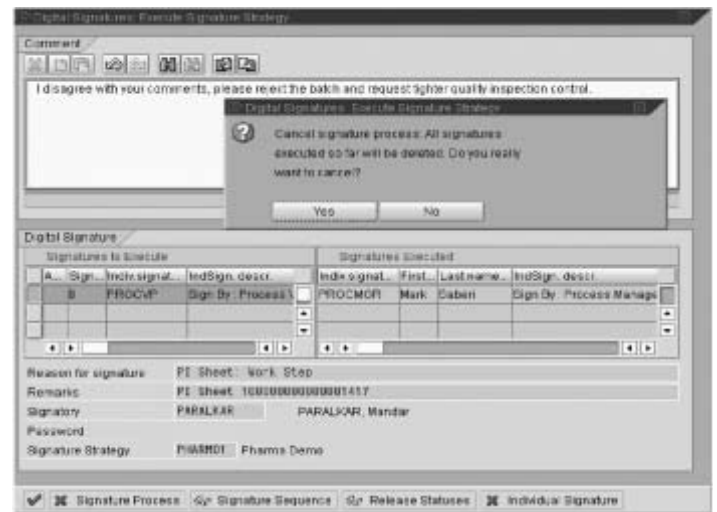


Figure 7: How a Signature Is Executed in mySAP ERP (Example PI-Sheet - CO60)

Date/Time	Signature	Invoic PI sheet	Invo. PIC	Linn.	Pict.	Mar.	Tabl.	Sign.	Characteristics View
20.10.2003 12:20:53	WANTHEY	1 1800300300031423	003	009	999	030	1	001	01
20.10.2003 16:05:12	DEVERMANN	1 1800300300031425	003	013	3000	030	1	001	01
20.10.2003 16:09:25	C038952	1 1800300300031425	003	109	999	030	1	001	01

Type/Reason for signature	Signature	Lastname, First name of signat. user	Lastname, first name user	Sig. date	Sig. time	Char. date	(Occur. fr.)
PI Sheet Work Elec	WANTHEY	WANTHEY, Arne	WANTHEY WANTHEY Arne	23.10.2003	12:20:53	20.10.2003	11:29:53
PI Sheet Work Elec	DEVERMANN	DEVERMANN, Nicola	C038952 Hader, Stephan	23.10.2003	16:05:12	20.10.2003	14:05:13
PI Sheet Work Elec	C038952	Hader, Stephan	C038952 Hader, Stephan	23.10.2003	16:09:25	20.10.2003	14:09:25

Figure 8: The Electronic Record of a Signature

ENCAPSULATED SIGNATURE TOOL IN mySAP ERP

A new feature in mySAP ERP is the inclusion of an encapsulated signature tool. This powerful functionality enables customers to include signature functionality in any transaction or business process within mySAP ERP. Additional benefits of the signature tool are:

- Further modularization of e-signatures
- Easier implementation of e-signatures in new processes
- Creation of a uniform flexible programming interface. Tools can be integrated into any business areas either in mySAP ERP or in other systems, such as SAP Supply Chain Management (and its subcomponent SAP Advanced Planning & Optimization) or SAP Customer Relationship Management.

All transactions and workflow of mySAP ERP can include signature functionality with the new encapsulated signature tool. For further information refer to the implementation guide entitled *Digital Signature Tool*.

DATE AND TIME STAMP FOR SIGNATURE

mySAP ERP uses the application server's time as the global date and time stamp for signatures. The application server's time is unique and unequivocal.

The local date and time stamp for the electronic record of a signature is available but it must be configured. The local date and time stamp is calculated from the application server's time. Daylight savings time rules and the time zone are maintained within the user's profile.

Comment 101 in the preamble of Part 11 discusses date and time local to the signer. In recent years, FDA has expressed at various industry forums that this is not required as long as the global date and time is unique and unequivocal and procedures are in place to correctly interpret the local time.

HOW DOES mySAP ERP COMPLY WITH PART 11?

The following table summarizes how mySAP ERP complies with each requirement of Part 11.

PART 11 CLAUSE	COMMENTS
11.10(a)	All electronic records within mySAP® ERP provide adequate audit trails that can be reviewed for information. These records are secured from unauthorized access.
11.10(b)	All electronic records generated in mySAP ERP are accurate, complete, and presented in a human readable format.
11.10(b)	mySAP ERP electronic records can be printed or exported into several industry-standard formats such as Adobe PDF and XML.
11.10(c)	All electronic records can be maintained in the active database or archived to accommodate all required retention periods even when software is upgraded. Access to these records is secured using standard SAP® authorization profiles. In addition, mySAP ERP maintains the link between electronic signatures executed to electronic records even after archiving.
11.10(d)	Robust security administration and authorization profiles assure system access. Changes to security profiles are recorded in mySAP ERP.
11.10(e)	mySAP ERP automatically generates all electronic records for creating, modifying, or deleting data. These records are date and time stamped and include the user ID of the individual who is logged on the system and performed the action. Electronic records also maintain the old and new values of the change and the transaction used to generate the record.
11.10(e)	Complementing the requirement in 11.10(c), all electronic records can be maintained in the active database or archived to accommodate all required retention periods. In addition, mySAP ERP maintains the link between electronic signatures executed to electronic records.
11.10(f)	Process instruction (PI) sheets used in manufacturing execution include sequence enforcement (operational checks) to enforce permitted sequencing of steps and events, as appropriate.

PART 11 CLAUSE	COMMENTS
11.10(g)	mySAP ERP executes authority checks in conjunction with its robust security administration and authorization profiles to ensure only authorized individuals can access the system, electronically sign a record, and access or perform the operation at hand. mySAP ERP also records changes to authorization profiles.
11.10(h)	Input devices such as terminals, measurement devices, and process control systems, in addition to remote logon are maintained through the same SAP security administration features and require authorization profiles for connection to mySAP ERP. In addition, device checks such as device type (for example a weigh scale with specified range) and device status (such as calibrated) can be managed and controlled via mySAP ERP classification features to determine the validity of the source of information.
11.10(i)	The <i>Quality Management Manual</i> for SAP development requires that all personnel responsible for developing and maintaining mySAP ERP have the education, training, and experience to perform their assigned tasks. A wide range of additional education and training offerings and regular assessments of individual training requirements ensure a process of continuous learning for SAP staff involved in the development and support of all SAP software.
11.10(j)	This clause covers a procedural requirement for customers and is not related to the functions or capabilities of mySAP ERP.
11.10(k)	The mySAP ERP document management system, which is part of mySAP Product Lifecycle Management (mySAP PLM), can provide controls over the distribution, access, and use of documentation for system operation and maintenance. In addition, mySAP ERP maintains the electronic records (audit trail) for revision and change control according to clause 11.10(e). Use of SAP online documentation and the knowledge warehouse capability requires procedural controls by customers to ensure compliance with this clause.
11.30	For open systems, mySAP ERP supports interfaces with complementary software partners that supply cryptographic methods such as public key infrastructure (PKI) technology.
11.50(a)	<p>Electronic signature records within mySAP ERP contain the following information:</p> <ul style="list-style-type: none"> ▪ The printed name of the signer ▪ The date and time when the signature was executed, including the date and time local to the signer when multiple time zones are involved (see comment 101 in the preamble of Part 11) ▪ The meaning (such as review, approval, responsibility, or authorship) associated with the signature <p>mySAP ERP automatically records the meaning associated with the signature with standard descriptions of the activity the signature performed (inspection lot approval, results recording, and so on). In addition, customers can use the comment field to expand or clarify the meaning of the signature.</p>
11.50(b)	Electronic signature records are maintained in the same manner as all electronic records and can be displayed or printed in a human readable format.
11.70	Electronic records of signatures are permanently linked to the executed electronic record. This link cannot be removed, copied, or transferred to falsify other electronic records by any ordinary means. As stated previously, this link remains when the electronic records are archived.
11.100(a)	mySAP ERP user and security administration functions provide robust system checks and configurable security procedures to establish and maintain a unique signature for each individual. This includes the prevention of reallocating a signature and deleting information relating to the electronic signature once it has been used.
11.100(b)	This clause covers a procedural requirement for customers and is not related to the functions or capabilities of mySAP ERP.
11.100(c)	This clause covers a procedural requirement for customers and is not related to the functions or capabilities of mySAP ERP.
11.200(a)(1)	<p>mySAP ERP requires two distinct components – a user ID and a password – to perform each and every electronic signature. By design, mySAP ERP does not support continuous sessions where only a single component is necessary subsequent to the first signing.</p> <p>For signatures executed outside of manufacturing (PP-PI) the user ID of the person logged on to the current session is defaulted only. When executing a signature, this user ID can be deleted and replaced by a different user. mySAP ERP will require the user ID and the corresponding password to authenticate the identity of each user. The user who successfully executed the signature will be recorded in the electronic record of the signature. Procedural controls must be in place to manage this process accordingly.</p>

PART 11 CLAUSE	COMMENTS
11.200(a)(2)	This clause covers a procedural requirement for customers and is not related to the functions or capabilities of mySAP ERP.
11.200(a)(3)	mySAP ERP user and security administration functions ensure that the attempted use of an individual's electronic signature other than the genuine owner requires the collaboration of two or more individuals.
11.200(b)	mySAP ERP provides a certified interface to biometric devices such as fingerprint and retinal scanning devices. Look for certified vendors in the SAP Complementary Software Program.
11.300(a)	mySAP ERP user and security administration functions provide the necessary controls to ensure that no two individuals have the same combination of identification code (user ID) and password.
11.300(b)	mySAP ERP can be configured to force users to change passwords at various intervals and it provides system checks to prevent users from repeating passwords or using combinations of alphanumeric characters that are included in the user ID. User IDs can also be invalidated, for example, when an employee leaves the company.
11.300(c)	This clause covers a procedural requirement for customers and is not related to the functions or capabilities of mySAP ERP.
11.300(d)	<p>mySAP ERP provides the following features to satisfy 11.300(d):</p> <ul style="list-style-type: none"> ▪ When the number of failed attempts (for either logon or signature) is exceeded, mySAP ERP prevents the user from further access without intervention from the security administration. Note: the number of failed attempts allowed is configurable. ▪ mySAP ERP generates an express mail within SAPOffice and sends it to a defined distribution list to notify the security administration "in an immediate and urgent manner." In addition, any MAPI-compliant messaging system can be interfaced to mySAP ERP to send this message externally to e-mail systems such as Microsoft Exchange or even a paging system. ▪ An electronic record of all failed attempts (for either logon or signature) is maintained in the Security Audit Log. mySAP ERP also generates electronic records for the locking and unlocking of users.
11.300(e)	This clause covers a procedural requirement for customers and is not related to the functions or capabilities of mySAP ERP.

Table 2: Part 11 Clause with mySAP[®] ERP

OTHER INTERNATIONAL GMP GUIDELINES WITH SIMILAR PART 11 REQUIREMENTS AND mySAP ERP

EU GMP GUIDELINE

EU Directive 91/356 delineates the legal requirements for European Union (EU) GMP. These obligations include a requirement to maintain a system of documentation. The main requirements affecting electronic records are that the data is available in readable form, that the data is available for the required time, and that the data is protected against loss or damage.

The objective of this guideline is to provide requirements for ensuring reliability in using the electronic record and electronic signature systems in those contexts.

PIC/S GUIDANCE

PIC/S published a guidance on “Good Practices for Computerized Systems in Regulated GxP Environments” in August 2003. The objective of this guidance is to provide background information and recommendations regarding computerized systems during the inspection of computerized systems and for training purposes. This guidance contains a section on electronic records and signatures aligned to EU GMP expectations.

ICH GUIDELINE

ICH Q7A Guideline “Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients” is the first GMP guideline that has been harmonized for the United States, EU, and Japan. ICH Q7A has been published as Annex 18 in EU GMP Guideline in July 2001. In addition, ICH Q7A has been adopted by Australia, Japan, and PIC/S.

Appendices 4 and 5 provide summary tables that describe how mySAP ERP complies with EU-GMP/PIC/S and ICH guidelines in comparison to the Part 11 rule.

SOFTWARE QUALITY

SAP has maintained ISO 9001 certification since 1994, and the SAP development department is certified according to the latest version, which is ISO 9001:2000. The corresponding quality management system shares best practices with the employees in its scope and includes all standards, which control the structured development life cycle in place. The standards are binding for all employees of development and ensure that SAP solutions are checked for completeness and correctness against standardized checklists, have a standard quality when released, and are introduced to the market according to a defined process. The process standards describing the development phases are SAP's standard operating procedures. In addition, product standards define the quality criteria for SAP software. All deliverables of the life-cycle phases are defined in a master list. The adherence to the process and product standards is documented in an internal system. Quality gates between the phases ensure that the activities and deliverables defined by the master list are complete.

mySAP ERP has been developed according to this development life cycle. Audits of SAP development are carried out numerous times each year by individual companies as well as industry groups such as the Pharmaceutical Validation Group (PVG). Pursuant to FDA's general principle of validation and given the fact that SAP is a highly configurable software solution, **the mySAP ERP configuration must be validated according to predetermined business requirements.** Therefore, to establish documentary evidence that provides a high degree of assurance that the configured system performs as intended, a validation methodology as part of a recognized development life cycle must be deployed.

VALIDATION OF mySAP ERP IN AN FDA-REGULATED ENVIRONMENT

SAP SOLUTION MANAGER

The SAP Solution Manager tool is a platform that provides the integrated content, tools, and methodologies you need to implement, support, operate, and monitor your enterprise's solutions in the pharmaceutical industry.

With SAP Solution Manager you can manage your SAP solution throughout the entire life cycle to ensure reliability, reduce TCO, and increase return on investments (ROI). Features and functions of SAP Solution Manager include:

- User requirement specification (URS) documents are the descriptions of the functionalities that the customer wants to run in the system. These documents can be managed with SAP Solution Manager.
- The road map of SAP Solution Manager fully supports the documentation of the different phases of the project, including predefined accelerators with versioning and status management.
- The business blueprint phase of SAP Solution Manager allows the management and documentation of all kinds of templates, documents, and so on with versioning, status management, and definition of electronic signatures.
- The platform integrates content, tools, and methods for implementation, support, operation, and control.
- Central administration is enabled, which provides control of allocated, decentralized applications.
- Automatic functions evaluate problems.

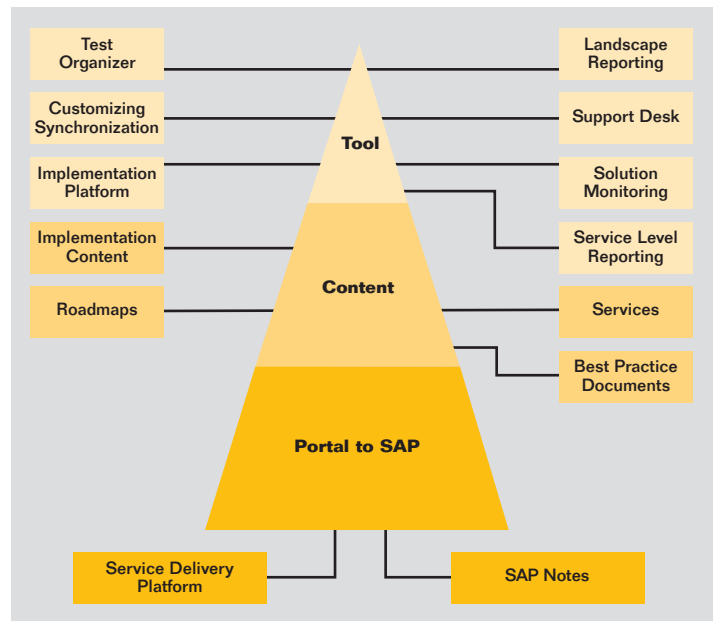


Figure 9: SAP Solution Manager

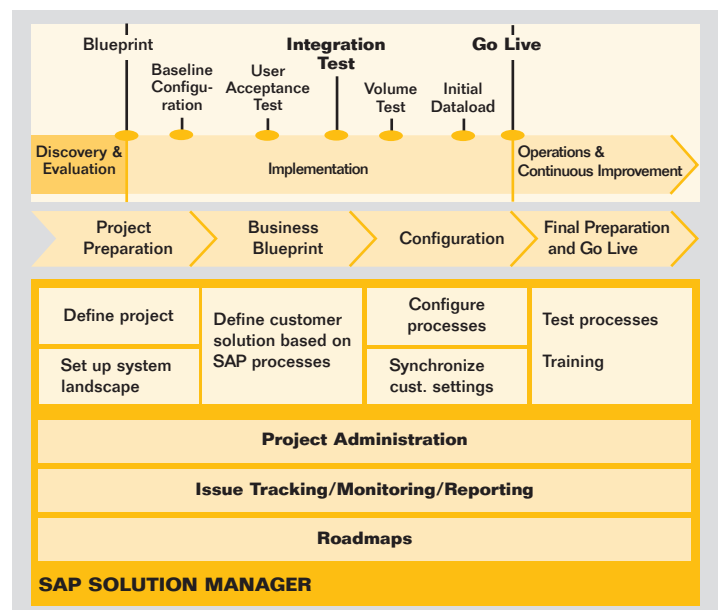


Figure 10: Implementing SAP Solutions – Process in Detail Along the Life Cycle

VALIDATION SERVICE MAP

The Validation Service Map provides links to the AcceleratedSAP™ (ASAP™) methodology’s nomenclature including the necessary project steps with links to available services and products from SAP to the GAMP nomenclature.

The Validation Service Map provides information concerning tools and services to SAP customers to support validation and to reduce TCO.

Refer to SAP Service Marketplace > alias “Solutionmaps”> Industry-specific business maps > Pharmaceuticals Solution Map.

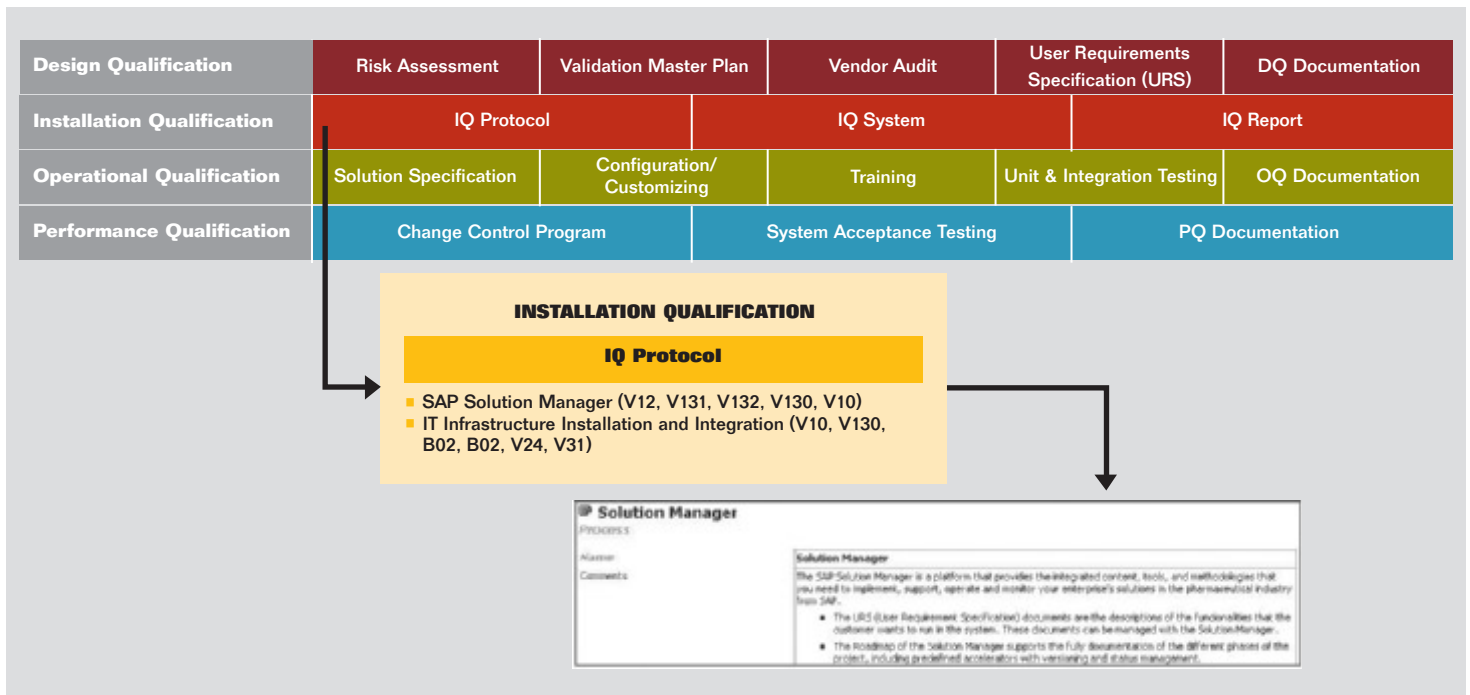


Figure 11: Validation Service Map, Edition 2004

GAMP V-MODEL AND AVAILABLE SAP TOOLS

Figure 12 shows a high-level representation of this methodology. The “V-model” is a high-level concept illustration first introduced by the Good Automated Manufacturing Practice (GAMP) Forum that was established by representatives from major international companies to interpret and improve the understanding of regulations for the development, implementation, and use of automated systems in pharmaceutical manufacturing. This “V-model” has been enhanced to more closely represent the ASAP methodology, but it remains consistent with the formally recognized software development life cycle.

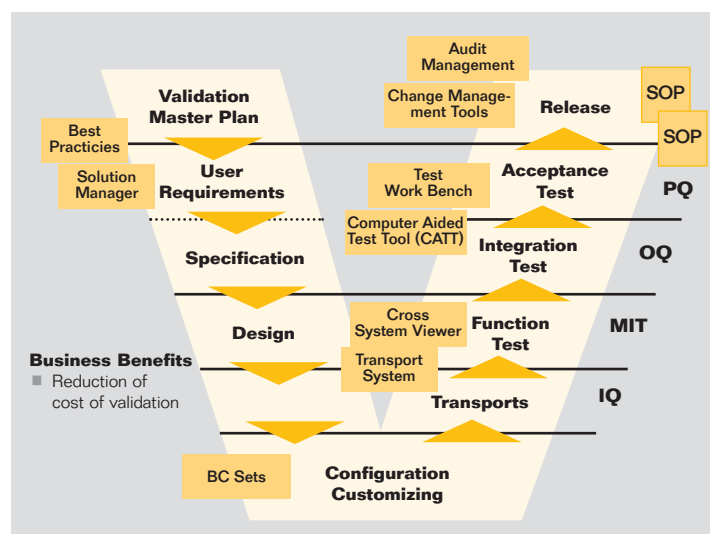


Figure 12: Enhanced V-Model Highlighting the ASAP Methodology and Available SAP Tools

Validation Approach to Achieve Part 11 Compliance

In the Part 11 preamble (specifically comments 64 through 68), FDA discusses the validation of electronic systems and acknowledges the complexity and controversy of validating commercial software. The agency also reiterates its general principle of validation that “planned and expected performance is based upon predetermined design specifications.” The following sections discuss the validation requirements both inferred and stated within §11.10(a).

Key activities necessary to validate mySAP ERP in compliance with Part 11 are:

- Conduct system risk assessment:
 - GxP evaluation
 - Determine whether the computerized system is regulated by any GxP predicate rules
 - Criticality assessment
 - Determine criticality of the computerized system based upon the processes and data it manages or supports
 - Complexity assessment
 - Determine complexity of the computerized system based upon technology, resources, software, and infrastructure requirements
 - Determine validation level
 - The level of validation for the computerized system is determined by the results of the previous evaluation and assessments.
 - Identify software category (such as GAMP 4.0).
 - Determine deliverables
 - Validation deliverables will be based upon each organization’s internal requirements and the assessment results.
- Define Part 11 requirements in:
 - Validation master plan (VMP)
 - Operational qualification (OQ)
- Conduct GxP assessment at the business process level (such as a transaction):
 - Determine GxP-relevant business processes and SAP R/3 objects
 - GxP relevance can be determined at the transaction, object, or field level.
- Configure software to activate complete audit trail reporting and electronic signatures

- Develop security authorizations according to software development life cycle (SDLC). Establish functional requirements specification for job roles:
 - Use the Business Process Master List (BPML) as the only source of authorization profile development. This ensures that unused, nonvalidated business processes within mySAP ERP are effectively blocked from unauthorized access.
 - Profiles should be managed similarly to configuration in regards to change control and the Transport Management component.
- Test the system:
 - Formal testing of Part 11 requirements should be based upon risk assessment results.
 - Create test objectives to demonstrate 21 CFR Part 11 compliance for each relevant clause of the regulation (for example, §11.10 (b) challenges the creation of an accurate and complete electronic record).
 - System testing of profiles should include negative testing of business-critical transactions (for example, cGMP). See Appendix 3 for a suggested list of cGMP-critical transactions.
- Train the users:
 - Ideally, users should be trained for all transactions within their profile(s) (ref. §11.10 (i)).

It is important to recognize the impact of the interpretation of §11.10 (b), specifically the word “complete,” as it pertains to electronic records generated in mySAP ERP. To identify where Part 11 applies, a GxP assessment must be performed. Before conducting this assessment, however, a strategy must be established to define at what level relevance to GxP will be assigned – the transaction or object level (for example, process order, material master, and so on) or at the field level (for example, order quantity, but not scheduling margin key for process order). This strategy is directly related to how the term “complete” is interpreted – either all the data contained within the transaction or object itself or only the data determined to be GxP relevant. It is important to understand the impact of each approach both from a compliance and system performance perspective.

GxP relevance at the object level may significantly reduce the risk of potential challenges to the system’s compliance because the boundaries of GxP and non-GxP are more clearly defined. Examples include a process order versus a planned order or a resource versus a capacity. However, this approach increases the amount of required configuration and can potentially affect system performance.

GxP assessment at the field level requires fewer configurations and does not affect system performance. However, this approach potentially increases the risk of challenges to the system’s compliance. Establishing GxP relevance at the field level increases the granularity to which mySAP ERP can be scrutinized – potentially invoking challenges field by field within transactions and master data objects. Additional written justification is required to clearly explain the assessment of why certain fields are not GxP relevant. This approach can also be challenged with the technical argument that SAP’s integrated infrastructure maintains both GxP and non-GxP data within the same database tables and business processes. Therefore, all data within these tables and transactions are subject to the same level of control to protect the integrity of the GxP data.

With respect to security and training, it is important to recognize the intent of §11.10 (i) is to ensure that persons have the wherewithal to competently execute and complete all of their assigned tasks. A potential compliance issue is the interpretation of “assigned tasks” and how job roles and authorizations may be developed and assigned within mySAP ERP. As part of their assigned job role within mySAP ERP, employees may have authorization for various transactions that they themselves do not use, but are included for other persons with the same assigned job role that require these authorizations. Therefore, a person may have authorization for transactions or “tasks” that have been assigned to their job profile, but for which they have not been trained.

CONCLUSION

Based upon the interpretation of the Part 11 rule and the functions and features discussed within this document, SAP AG believes that mySAP ERP technically complies with the intent and requirements of 21 CFR Part 11 and several international good manufacturing practice (GMP) guidelines. Releases of SAP R/3 prior to release 4.6C can be compliant depending on the scope of functionality and the configuration and customization implemented.

SAP continues its long-standing partnership with the life sciences industry and provides technology, tools, and solutions to its pharmaceutical, medical diagnostics and devices, and biotechnology customers. mySAP ERP provides a “win-win” opportunity for customers to promote FDA compliance while reducing their costs and maximizing their return on investment.

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APPENDICES

APPENDIX 1: SAP/FDA cGMP FUNCTIONALITY MATRIX FOR FINISHED PHARMACEUTICALS

SAP ERP PHARMACEUTICAL cGMP 21 CFR PART 211	MATERIALS MANAGEMENT	WAREHOUSE MANAGEMENT	PRODUCTION PLANNING PROCESS INDUSTRIES
SUBPART D EQUIPMENT			<ul style="list-style-type: none"> ▪ Data Backup & Recovery ▪ Electronic/Digital Signature ▪ Engineering Change Management ▪ Process Instruction Sheets ▪ Resource/Equipment Mgmt ▪ Security & Authorizations ▪ Sequence Enforcement
SUBPART E CONTROL OF COMPONENTS AND DRUG PRODUCT CONTAINERS AND CLOSURES	<ul style="list-style-type: none"> ▪ Approved Vendors List ▪ Bar Code Interface ▪ Batch Management ▪ Engineering Change Management ▪ Expiration Dating ▪ Container Management ▪ Inventory Management ▪ Quarantine System 	<ul style="list-style-type: none"> ▪ Bar Code Interface ▪ Inventory Management ▪ Quarantine System ▪ Container Management 	<ul style="list-style-type: none"> ▪ Batch Determination ▪ Engineering Change Management ▪ Active Ingrid. Mgmt
SUBPART F PRODUCTION AND PROCESS CONTROLS	<ul style="list-style-type: none"> ▪ Bar Code Interface ▪ Batch Management ▪ Engineering Change Management ▪ Container Management ▪ Inventory Management ▪ Quarantine System ▪ Picking List ▪ Approved Vendors List 	<ul style="list-style-type: none"> ▪ Bar Code Interface ▪ Inventory Management ▪ Quarantine System ▪ Container Management ▪ Task and Resource Management 	<ul style="list-style-type: none"> ▪ Batch Determination ▪ Document Mgmt System Interface ▪ Electronic Batch Record ▪ Electronic/Digital Signature ▪ Engineering Change Management ▪ Order Management ▪ Active Ingrid. Mgmt ▪ PI-PCS & OPC Interface (SAP-ODA) ▪ Process Instruction Sheets ▪ Process Operator Cockpit ▪ Recipe Management ▪ Resource/Equipment Mgmt ▪ Sequence Enforcement ▪ Statistical Process Control (SPC) ▪ Subcontract Manufacturing ▪ Picking List
SUBPART G PACKAGING AND LABELING CONTROL	<ul style="list-style-type: none"> ▪ Bar Code Interface ▪ Batch Management ▪ Engineering Change Management ▪ Expiration Dating ▪ Container Management ▪ Inventory Management ▪ Quarantine System 	<ul style="list-style-type: none"> ▪ Bar Code Interface ▪ Inventory Management ▪ Quarantine System ▪ Container Management ▪ Global Label Management 	<ul style="list-style-type: none"> ▪ Batch Determination ▪ Document Mgmt System Interface ▪ Electronic Batch Record ▪ Electronic/Digital Signature ▪ Engineering Change Management ▪ Order Management ▪ Label Reconciliation ▪ Process Instruction Sheets ▪ PI-PCS & OPC Interface (SAP-ODA) ▪ Sequence Enforcement

QUALITY MANAGEMENT	PLANT MAINTENANCE	SALES & DISTRIBUTION
<ul style="list-style-type: none"> ■ Test Equipment Calibration ■ Electronic/Digital Signature ■ Engineering Change Management ■ Equipment Notifications 	<ul style="list-style-type: none"> ■ Plant Equipment Calibration ■ Engineering Change Management ■ Equipment Management ■ Equipment Status Logbook ■ Preventative Maintenance ■ PM-PCS 	
<ul style="list-style-type: none"> ■ Electronic/Digital Signature ■ Engineering Change Management ■ Goods Receipt Inspection ■ Nonconformance Reporting ■ QM-IDI Interface to LIMS ■ Quality Disposition ■ Sample Management ■ Source Inspection ■ Statistical Quality Control (SQC) ■ Supplier Quality Management 		
<ul style="list-style-type: none"> ■ Electronic/Digital Signature ■ Engineering Change Management ■ Incoming/Receiving Inspection ■ In-Process Inspection ■ Nonconformance Reporting ■ Post-Process Inspection ■ QM-IDI Interface to LIMS ■ Quality Disposition ■ Sample Management ■ Statistical Process Control (SPC) ■ Statistical Quality Control (SQC) ■ Quality Notifications ■ Supplier Quality Management 	<ul style="list-style-type: none"> ■ Calibration ■ Engineering Change Management ■ Equipment Management ■ Equipment Status Logbook ■ PM-PCS 	
<ul style="list-style-type: none"> ■ Electronic/Digital Signature ■ Engineering Change Management ■ Goods Receipt Inspection ■ In-Process Inspection ■ Nonconformance Reporting ■ Post-Process Inspection ■ Quality Disposition ■ Sample Management ■ Statistical Quality Control (SQC) 	<ul style="list-style-type: none"> ■ Calibration ■ Engineering Change Management ■ Equipment Management ■ Equipment Status Logbook 	

SAP ERP PHARMACEUTICAL cGMP 21 CFR PART 211	MATERIALS MANAGEMENT	WAREHOUSE MANAGEMENT	PRODUCTION PLANNING PROCESS INDUSTRIES
SUBPART H HOLDING AND DISTRIBUTION	<ul style="list-style-type: none"> ■ Bar Code Interface ■ Batch Management ■ Batch Where-Used List ■ Container Management ■ Inventory Management ■ Quarantine System 	<ul style="list-style-type: none"> ■ Bar Code Interface ■ FIFO & FEFO Removal Strategies ■ Container Management ■ Inventory Management ■ Quarantine System 	
SUBPART I LABORATORY CONTROLS			
SUBPART J RECORDS AND REPORTS	<ul style="list-style-type: none"> ■ Material Documents ■ Batch Where-Used List ■ Logistics/Purchasing Info System 	<ul style="list-style-type: none"> ■ Transfer Orders ■ Inventory Info System 	<ul style="list-style-type: none"> ■ Electronic Batch Record ■ Electronic/Digital Signatures ■ Engineering Change Management ■ Master Recipe ■ Process Instruction Sheets ■ Process Orders ■ Change Docs/Audit Trails ■ Shop Floor Info System ■ Order Info System
SUBPART K RETURNED AND SALVAGED DRUG PRODUCTS	<ul style="list-style-type: none"> ■ Container Management ■ Inventory Management ■ Quarantine System ■ Material Reconciliation 	<ul style="list-style-type: none"> ■ Container Management ■ Inventory Management ■ Quarantine System ■ Material Reconciliation 	

QUALITY MANAGEMENT	PLANT MAINTENANCE	SALES & DISTRIBUTION
		<ul style="list-style-type: none"> ▪ Batch Determination
<ul style="list-style-type: none"> ▪ Calibration ▪ Electronic/Digital Signature ▪ Engineering Change Management ▪ Equipment Management ▪ Incoming/Receiving Inspection ▪ In-Process Inspection ▪ Inspection Methods ▪ Nonconformance Reporting ▪ Post-Process Inspection ▪ QM-IDI Interface to LIMS ▪ Quality Disposition ▪ Recurring Inspection ▪ Sample Management ▪ Statistical Quality Control (SQC) ▪ Test Specification Mgmt ▪ Stability Studies 	<ul style="list-style-type: none"> ▪ Calibration ▪ Engineering Change Management ▪ Equipment Management ▪ Equipment Status Logbook 	
<ul style="list-style-type: none"> ▪ Complaint Management ▪ Electronic/Digital Signatures ▪ Engineering Change Management ▪ Inspection Lots ▪ Inspection Plans ▪ Nonconformance Reporting ▪ Change Docs/Audit Trails ▪ Quality Info System 	<ul style="list-style-type: none"> ▪ Engineering Change Management ▪ Equipment Status Logbook ▪ Maintenance Orders ▪ Maintenance Task Lists ▪ Change Docs/Audit Trails ▪ Maintenance Info System 	<ul style="list-style-type: none"> ▪ Delivery Notes ▪ Sales Orders ▪ Sales/Shipment Info System
<ul style="list-style-type: none"> ▪ Returns Inspection ▪ Complaint Management ▪ QM-IDI Interface to LIMS ▪ Electronic/Digital Signature ▪ Quality Disposition ▪ Statistical Quality Control (SQC) 		<ul style="list-style-type: none"> ▪ Return Goods Authorization

APPENDIX 2: SAP/FDA cGMP FUNCTIONALITY MATRIX FOR MEDICAL DEVICES

SAP ERP MEDICAL DEVICE QSR 21 CFR PART 820	MATERIALS MANAGEMENT	WAREHOUSE MANAGEMENT	PRODUCTION PLANNING PRODUCTION PLANNING PROCESS INDUSTRIES
SUBPART C DESIGN CONTROLS	<ul style="list-style-type: none"> ■ Bills of Materials ■ Substance, Dangerous Goods ■ Electronic/Digital Signature ■ Engineering Change Management ■ Material Master Records 		<ul style="list-style-type: none"> ■ Electronic/Digital Signature ■ Engineering Change Management ■ Master Recipe ■ Process Instruction Sheets ■ Routings ■ Statistical Process Control (SPC) ■ Security & Authorizations
SUBPART D DOCUMENT CONTROLS	<ul style="list-style-type: none"> ■ Document Mgmt System Interface ■ Engineering Change Management 		<ul style="list-style-type: none"> ■ Document Mgmt System Interface ■ Engineering Change Management
SUBPART E PURCHASING CONTROLS	<ul style="list-style-type: none"> ■ Approved Vendors list 		
SUBPART F IDENTIFICATION AND TRACEABILITY	<ul style="list-style-type: none"> ■ Barcode Interface ■ Batch Management ■ Batch Where-Used List ■ Container Management ■ Shelf Life Expiration ■ Inventory Management ■ Quarantine System ■ Serial Number Management 	<ul style="list-style-type: none"> ■ Barcode Interface ■ Container Management ■ Inventory Management ■ Quarantine System ■ Container Management 	<ul style="list-style-type: none"> ■ Electronic Batch Record
SUBPART G PRODUCTION AND PROCESS CONTROLS	<ul style="list-style-type: none"> ■ Barcode Interface ■ Batch Management ■ Container Management ■ Engineering Change Management ■ Inventory Management ■ Picking List ■ Quarantine System ■ Serial Number Management 	<ul style="list-style-type: none"> ■ Barcode Interface ■ Container Management ■ Inventory Management ■ Quarantine System ■ Task & Resource Management 	<ul style="list-style-type: none"> ■ Batch Determination ■ Document Mgmt System Interface ■ Electronic Batch Record ■ Electronic/Digital Signature ■ Engineering Change Management ■ In-Process Inspection ■ Order Management ■ PI-PCS & OPC Interface (SAP-ODA) ■ Process Instruction Sheets ■ Process Operator Cockpit ■ Recipe Management ■ Resource/Equipment Mgmt ■ Sub-Contract Manufacturing ■ Sequence Enforcement ■ Statistical Process Control (SPC)

QUALITY MANAGEMENT	PLANT MAINTENANCE	SALES & DISTRIBUTION
<ul style="list-style-type: none"> ▪ Electronic/Digital Signature ▪ Incoming/Receiving Inspection ▪ In-Process Inspection ▪ Nonconformance Reporting ▪ Post-Process Inspection ▪ QM-IDI Interface to LIMS ▪ Quality Disposition ▪ Statistical Process Control (SPC) ▪ Statistical Quality Control (SQC) 		
<ul style="list-style-type: none"> ▪ Document Mgmt System Interface ▪ Engineering Change Management 	<ul style="list-style-type: none"> ▪ Document Mgmt System Interface ▪ Engineering Change Management 	
<ul style="list-style-type: none"> ▪ Electronic/Digital Signature ▪ Engineering Change Management ▪ Quality Information Records ▪ Quality Notifications ▪ Supplier Quality Management 		
<ul style="list-style-type: none"> ▪ Test Equipment Calibration ▪ Electronic/Digital Signature ▪ Engineering Change Management ▪ Equipment Management ▪ Incoming/Receiving Inspection ▪ In-Process Inspection ▪ Nonconformance Reporting ▪ Post-Process Inspection ▪ QM-IDI Interface to LIMS ▪ Sample Management ▪ Statistical Process Control (SPC) ▪ Statistical Quality Control (SQC) 	<ul style="list-style-type: none"> ▪ Plant Equipment Calibration ▪ Engineering Change Management ▪ Equipment Management ▪ Equipment Status Logbook ▪ Preventative Maintenance 	

SAP ERP MEDICAL DEVICE QSR 21 CFR PART 820	MATERIAL MANAGEMENT	WAREHOUSE MANAGEMENT	PRODUCTION PLANNING PRODUCTION PLANNING PROCESS INDUSTRIES
SUBPART H ACCEPTANCE ACTIVITIES			
SUBPART I NONCONFORMING PRODUCT	<ul style="list-style-type: none"> ■ Batch Management ■ Container Management ■ Inventory Management ■ Quarantine System 	<ul style="list-style-type: none"> ■ Container Management ■ Inventory Management ■ Quarantine System ■ Returns Handling 	<ul style="list-style-type: none"> ■ Electronic Batch Record ■ Rework Orders
SUBPART J CORRECTIVE AND PREVENTATIVE ACTION	<ul style="list-style-type: none"> ■ Container Management ■ Inventory Management ■ Quarantine System 	<ul style="list-style-type: none"> ■ Container Management ■ Inventory Management ■ Quarantine System ■ Lot Geneology (Batch Tracking) 	
SUBPART K LABELING AND PACKAGING CONTROL	<ul style="list-style-type: none"> ■ Barcode Interface ■ Batch Management ■ Engineering Change Management ■ Expiration Dating ■ Container Management ■ Inventory Management ■ Quarantine System 	<ul style="list-style-type: none"> ■ Barcode Interface ■ Container Management ■ Inventory Management ■ Quarantine System ■ Global Label Management 	<ul style="list-style-type: none"> ■ Batch Determination ■ Document Mgmt System Interface ■ Electronic Batch Record ■ Electronic/Digital Signature ■ Engineering Change Management ■ In-Process Inspection ■ Label Reconciliation ■ Order Management ■ PI-PCS & OPC Interface (SAP-ODA) ■ Process Instruction Sheets ■ Sequence Enforcement

QUALITY MANAGEMENT	PLANT MAINTENANCE	SALES & DISTRIBUTION
<ul style="list-style-type: none"> ▪ Electronic/Digital Signature ▪ Engineering Change Management ▪ Incoming/Receiving Inspection ▪ In-Process Inspection ▪ Inspection Methods ▪ Nonconformance Reporting ▪ Stability Studies ▪ Post-Process Inspection ▪ QM-IDI Interface to LIMS ▪ Quality Disposition ▪ Sample Management ▪ Source Inspection ▪ Statistical Quality Control (SQC) ▪ Test Specification Mgmt 		
<ul style="list-style-type: none"> ▪ Electronic/Digital Signature ▪ Nonconformance Reporting ▪ Quality Disposition ▪ Quality Inspection 		
<ul style="list-style-type: none"> ▪ Complaint Management ▪ Electronic/Digital Signature ▪ Nonconformance Reporting ▪ QM-IDI Interface to LIMS ▪ Quality Disposition ▪ CAPA – Root Cause Analysis ▪ Returns Inspection ▪ Statistical Quality Control (SQC) 		<ul style="list-style-type: none"> ▪ Return Goods Authorization
<ul style="list-style-type: none"> ▪ Electronic/Digital Signature ▪ Engineering Change Management ▪ Goods Receipt Inspection ▪ In-Process Inspection ▪ Nonconformance Reporting ▪ Post-Process Inspection ▪ Quality Disposition ▪ Sample Management ▪ Statistical Quality Control (SQC) 	<ul style="list-style-type: none"> ▪ Calibration ▪ Engineering Change Management ▪ Equipment Management ▪ Equipment Status Logbook 	

SAP ERP MEDICAL DEVICE QSR 21 CFR PART 820	MATERIAL MANAGEMENT	WAREHOUSE MANAGEMENT	PRODUCTION PLANNING PRODUCTION PLANNING PROCESS INDUSTRIES
SUBPART L HANDLING, STORAGE, DISTRIBUTION, AND INSTALLATION	<ul style="list-style-type: none"> ▪ Barcode Interface ▪ Batch Management ▪ Batch Where-Used List ▪ Container Management ▪ Inventory Management ▪ Quarantine System 	<ul style="list-style-type: none"> ▪ Barcode Interface ▪ Container Management ▪ FIFO & FEFO Removal Strategies ▪ Inventory Management ▪ Quarantine System ▪ Container Management 	
SUBPART M RECORDS	<ul style="list-style-type: none"> ▪ Bills of Materials ▪ Material Documents ▪ Logistics/Purchasing Info System 	<ul style="list-style-type: none"> ▪ Transfer Orders ▪ Inventory Info System 	<ul style="list-style-type: none"> ▪ Electronic Batch Record ▪ Electronic/Digital Signatures ▪ Engineering Change Management ▪ Master Recipe ▪ Process Instruction Sheets ▪ Process Orders ▪ Production Orders ▪ Routing ▪ Shopfloor Info Systems
SUBPART N SERVICING			
SUBPART O STATISTICAL TECHNIQUES			<ul style="list-style-type: none"> ▪ Statistical Process Control (SPC)

QUALITY MANAGEMENT	PLANT MAINTENANCE	SALES & DISTRIBUTION
<ul style="list-style-type: none"> ▪ Installation Inspection 	<ul style="list-style-type: none"> ▪ Equipment Management 	<ul style="list-style-type: none"> ▪ Batch Determination ▪ Delivery Notes ▪ Sales Orders
<ul style="list-style-type: none"> ▪ Complaint Management ▪ Electronic/Digital Signatures ▪ Engineering Change Management ▪ Inspection Lots ▪ Inspection Plans ▪ Nonconformance Reporting ▪ Quality Info System 	<ul style="list-style-type: none"> ▪ Engineering Change Management ▪ Equipment Status Logbook ▪ Maintenance Orders ▪ Maintenance Task Lists ▪ Maintenance Info System 	<ul style="list-style-type: none"> ▪ Delivery Notes ▪ Sales Orders ▪ Sales/Shipment Info System
<ul style="list-style-type: none"> ▪ Service Inspection ▪ Spare Parts Control 	<ul style="list-style-type: none"> ▪ Service Management ▪ Spare Parts Management 	
<ul style="list-style-type: none"> ▪ QM-STI Statistical Interface ▪ Sample Management ▪ Statistical Process Control (SPC) ▪ Statistical Quality Control (SQC) 		

**APPENDIX 3: FDA cGMP CRITICAL TRANSACTIONS
LIST FOR NEGATIVE TESTING OF SECURITY PROFILES**

TECHNICAL DATA		
1.	SU01	Maintain Authorizations
2.	SE38	Execute Program
MASTER DATA		
3.	MM01	Create Material
4.	MM02	Change Material
5.	MMDE	Delete All Materials
6.	ME01	Maintain Source List
7.	MSC1	Create Batch
8.	MSC2	Change Batch
9.	BMBC	Batch Management Cockpit
TRANSACTIONAL DATA		
10.	COR1	Create Process Order with Material
11.	COR2	Change Process Order
12.	QA01	Create Inspection Lot
13.	QA02	Change Inspection Lot
14.	QA08	Mass Change of QM Inspection Data
15.	QA11	Record Usage Decision
16.	QA12	Change Usage Decision
17.	QA14	Change Usage Decision Without History
18.	QA16	Collective Usage Decision for OK Lots
19.	QA32	Inspection Lot Selection
20.	QAC1	Correct Actual Quantity in Insp Lot
21.	QAC2	Transfer Insp. Lot Quant.
22.	QAC3	Insp. Lot - Reset Sample Calculation
23.	QE01	Record Results
24.	QE02	Change Results
25.	QE51	Worklist: Results Recording
26.	QVM1	Inspection Lots Without Inspection Completion
27.	QVM2	Inspection Lots with Open Quantities
28.	QVM3	Inspection Lots Without Usage Decision
29.	QM01	Create Quality Notification
30.	QM02	Change Quality Notification

**APPENDIX 4: COMPLIANCE SUMMARY TABLE OF EU AND PIC GMP GUIDELINES
FOR PART 11 REQUIREMENTS**

EU Annex 11/Annex 11 to PIC/S Document PH 1/97 (Rev. 3) SECTION	COMMENT
Personnel 1	This section is comparable to clause 11.10(i) in Part 11.
Validation 2	Validation is a procedural requirement for customers and is not related to the functions or capabilities of mySAP ERP. The SAP quality management system describes those phases of the software life cycle involved in developing and maintaining SAP software. mySAP ERP has been developed according to a formally recognized software development life cycle and has maintained ISO 9001 certification since 1994. ISO 9001 requirements cover the development, production, sales, and maintenance of products and services. This is comparable to clauses 11.10(e) and 11.10 (k) in Part 11.
System 3	This section is a procedural requirement for customers and is not related to the functions or capabilities of mySAP ERP.
System 4	This section is a procedural requirement for customers and is not related to the functions or capabilities of mySAP ERP.
System 5	The SAP quality management system describes those phases of the software life cycle involved in developing and maintaining SAP software. mySAP ERP has been developed according to a formally recognized software development life cycle and has maintained ISO 9001 certification since 1994. ISO 9001 requirements cover the development, production, sales, and maintenance of products and services.
System 6	mySAP ERP complies with these requirements. For example, warnings appear when users enter aberrant data, for example, when a user records results in quality management or records process data in process instruction sheets. The user is then prompted to confirm entry of this data before it is accepted. This is comparable to clause 11.10(h). Otherwise, this is a procedural requirement for customers and is not related to the functions or capabilities of mySAP ERP.
System 7	This section is a procedural requirement for customers and is not related to the functions or capabilities of mySAP ERP.
System 8	This section is comparable to clauses 11.10(d), 11.10(e), and 11.10(g) in Part 11.
System 9	See System 6 and clause 11.10(f).
System 10	This section is comparable to clauses 11.10(a), 11.10(e), and 11.50 (a) (b) in Part 11 with the exception that Annex 11 specifically requires a reason for change for all critical data. When critical data cannot be managed via ECM, the reason for change must be recorded by long text.
System 11	This section is a procedural requirement for customers and is not related to the functions or capabilities of mySAP ERP.
System 12	This section is comparable to clause 11.10(b) in Part 11.
System 13	This section concerns physical properties that are procedural requirements for customers and is not related to the functions or capabilities of mySAP ERP. It is comparable to clauses 11.10(c) and 11.70 in Part 11.
System 14	This section is a procedural requirement for customers and is not related to the functions or capabilities of mySAP ERP.
System 15	This section is a procedural requirement for customers and is not related to the functions or capabilities of mySAP ERP.
System 16	This section is a procedural requirement for customers and is not related to the functions or capabilities of mySAP ERP.
System 17	This section concerns the SAP quality management system for mySAP ERP and is comparable to clauses 11.10(e) and 11.10(k). Otherwise, it is a procedural requirement for customers and is not related to the functions or capabilities of mySAP ERP.
System 18	This section is a procedural requirement for customers and is not related to the functions or capabilities of mySAP ERP.
System 19	This section is comparable to clauses 11.10(d), 11.10(g), and 11.50(a) in Part 11.

APPENDIX 5: COMPLIANCE SUMMARY TABLE OF ICH Q7A GUIDELINE FOR PART 11 REQUIREMENTS

ICH Q7A Guideline/Annex 18 to the EU Guide to Good Manufacturing Practice	COMMENT
5.40	Validation is a procedural requirement for customers and is not related to the functions or capabilities of mySAP ERP. The SAP quality management system describes those phases of the software life cycle involved in developing and maintaining SAP software. mySAP ERP has been developed according to a formally recognized software development life cycle and has maintained ISO 9001 certification since 1994. ISO 9001 requirements cover the development, production, sales, and maintenance of products and services. This is comparable to clauses 11.10(e) and 11.10 (k) in Part 11.
5.41	The SAP quality management system describes those phases of the software life cycle involved in developing and maintaining SAP software. mySAP ERP has been developed according to a formally recognized software development life cycle and has maintained ISO 9001 certification since 1994. ISO 9001 requirements cover the development, production, sales, and maintenance of products and services.
5.42	This section is a procedural requirement for customers and is not related to the functions or capabilities of mySAP ERP.
5.43	This section is comparable to clauses 11.10(c), 11.10(d), 11.10(e), 11.10(g), 11.50(a)(b), and 11.70 in Part 11.
5.44	This section is comparable to clauses 11.10(e), 11.10(2) in Part 11.
5.45	mySAP ERP posts warnings when users enter aberrant data, when a user records results in quality management or records process data in process instruction sheets. mySAP ERP then prompts the user to confirm entry of this data before it is accepted. This is comparable to clauses 11.10(f) and 11.10(h) in Part 11.
5.46	This section is comparable to clauses 11.10(a), 11.10(b), 11.10(c), and 11.10(e) in Part 11.
5.47	This section is a procedural requirement for customers and is not related to the functions or capabilities of mySAP ERP.
5.48	This section is comparable to clause 11.10(c). Otherwise, it is a procedural requirement for customers and is not related to the functions or capabilities of mySAP ERP.
5.49	This section is a procedural requirement for customers and is not related to the functions or capabilities of mySAP ERP.

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