BEAS MANUFACTURING BASED ON SAP BUSINESS ONE® – Industrial Regulations

CONTENT

1. TODAY'S APPROACH TO COMPLIANCE

Boyum IT Solutions comply with various regulations, depending on which markets you do business in. These regulations include those of the U.S. Food and Drug Administration (FDA) – such as 21 CFR Part 11 Electronic Records; Electronic Signature – the European Commission's Annex 11 Computerized Systems, and Japan's PFSB Notification, No. 0401022, Electronic Records/Electronic Signature. Regulatory authorities across the globe have acknowledged the importance of computerized systems and records within the Life Sciences industry. These regulations all share the same intention of ensuring the integrity of electronic data and records.
However, applying these requirements to the numerous computerized systems within your Life Sciences company can translate into millions of dollars in project costs to validate these systems. Also, maintaining these systems in a "validated state" for their productive lifetime has significant annual costs.

System-based Inspection Approach

Around the globe, an increasing number of regulatory authorities are taking a risk-based approach to determine which computer systems are the most critical. They, then, follow a system-based approach that aims at conducting and evaluating inspections regarding specific systems to evaluate risks. For example, a global regulatory agency like the FDA's Inspection Compliance Program, which is similar to the other agencies' inspection programs, consists of six major systems:

- Quality system
- Facilities and equipment system
- Materials system
- Production system
- Packaging and labelling system
- Laboratory control system

These systems are not considered discrete entities – they are part of an integrated system model. The idea underlying this approach is that deficiencies in one system will affect all other systems as well. The integrated system-based inspection approach recognizes the widespread use of computers to support each company's quality initiatives. Therefore, regulatory agencies review the qualification, validation, and security of integrated computer solutions much more closely than those of standalone systems during an inspection.

2. KNOW THE RULES

Many functions and features of Beas Manufacturing support technical compliance with global electronic record and electronic signature (ERES) regulations.

ERES Requirements from global regulatory agencies

Many regulations deal with electronic records and electronic signatures.

FDA 21 CFR Part 11

FDA regulation 21 CFR Part 11 Electronic Records; Electronic Signatures; Final Rule (referred to here as Part 11) was the result of a six-year effort by the FDA (with input from the industry). The goal was to supply all FDA- -regulated companies with requirements on how to maintain paperless (that is, electronic) record systems while still complying with good clinical, laboratory and manufacturing practice. These include:

- Good manufacturing practice (GMP): 21 CFR 110 (food), 210 (drugs in general, also includes good manufacturing practice for biologics), 211 (finished pharmaceuticals) and 820 (medical devices)
- Good laboratory practice: 58
- Good clinical practice: 50, 54 and 56

The regulation also details specific requirements for electronic and digital signatures because the FDA considers these signatures to be legally binding.
Since its publication in 1997, this regulation has been subject to evolving interpretations by both the FDA and the industry. In February 2003, the FDA withdrew all Part 11 guidelines and the Compliance Policy Guide. The Part 11 rule is still valid, but these accompanying guidelines are withdrawn. The reasons for the withdrawal are discussed in the FDA document from August 2003, Guidance for Industry Part 11, Electronic Records; Electronic Signatures – Scope and Application, as follows:
"Concerns have been raised that some interpretations of the part 11 requirements would (1) unnecessarily restrict the use of electronic technology in a manner that is inconsistent with FDA's stated intent in issuing the rule, (2) significantly increase the costs of compliance to an extent that was not contemplated at the time the rule was drafted, and (3) 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."

FDA APPROVAL PROCESS

The FDA approval process consists of three stages:

- **Stage 1: Process Design** – This stage defines a commercial process based on knowledge gained through developmental procedures and scale-up activities.
- **Stage 2: Process Qualification** – This stage is responsible for evaluating and assessing if the concerned process is capable of commercial manufacturing that can be reproduced over a period of time, across all the batches.
- **Stage 3: Continued Process Verification –** In this stage, one can gain assurance that all the processes remain in a state of control through the routine production.

Each of these stages is responsible for creating an approach that delivers products ranking high on quality and consistencies across all batches. Different activities and tools are observed in each stage, some which are unique to them. It is highly recommended that relevant documentation and analytical methods are used through all the stages to maximize the benefits and results of process validation.

In simple terms, 21 CRF part 11 from FDA requires the companies to "implement controls, including audits, system validations, audit trails, electronic signatures, and documentation for software and systems involved in processing the electronic data that FDA predicate rules require them to maintain" (htt ps://en.wikipedia.org/wiki/ Title_21_CFR_Part_11).

The following explains how Beas Manufacturing, in combination with SAP Business One, addresses these requirements:

- **Audits and audit trails:**

Beas Manufacturing always keeps track of changes on documents and master data that can be accessed in a simple way for audit purposes. All transactions are registered and cannot be deleted, only cancelled, what keeps them available for auditing (SAP Business One model). The transactions related to batches or serial numbers are always linked to them (including quality and production documents), and can be retrieved at any time by using our batches and serial numbers' tracking report.

- **System validations:**

Beas Manufacturing has a very comprehensive function for configuring user rights, which can be used to define everything that the users will have (or will not have) rights to access. After setting up the rights for each user, they can be easily retrieved for auditing purposes.

- **Electronic signatures:**

Every transaction, document, or master data created on SAP Business One and Beas Manufacturing are signed by the users who created them. The access to SAP Business One is based on a user/password model, and Beas Manufacturing Terminals can also be configured to be accessed based on user/password. Besides, in Beas Manufacturing it is possible to define a specific electronic signature to release goods from quality control, which ensures that only authorized personnel can release the goods.

- **Documentation:**

Beas Manufacturing has documentation of all its functions that can be accessed from every window by pressing F1, from our help portal (http://help.boyum-it.com) and via the help page (http://help.beascloud.com/).

EU GMP Annex 11: Computerized Systems

The GMP guideline of the European Medicines Agency, Directive 2003/94/EC, delineates the legal requirements for good manufacturing practice in the EU, including the need to maintain a documentation system. The main requirements affecting electronic records are that the data is available in human-readable form, accessible for the required time, and protected against loss or damage. The objective of this guideline is to provide requirements to ensure reliability in using the electronic record and electronic signature systems in those contexts.

The new Annex 11 and EU GMP Chapter 4 requirements on generation, control and retention of documents are more current, effective July 2011. There are many similarities between the regulations of Annex 11 and Part 11 (and Part 11 Guidance). In general, they both include information addressing risk management, personnel, validation, system management and documentation, software, data, security, audit trails, signatures, printouts and data storage.

Annex 11 introduces new categories that encompass infrastructure, as well as fine-tunes requirements and interpretations. For example, Annex 11 expands computerized systems to include qualification of the IT infrastructure. Part 11 mentions protection of records. In addition, Annex 11 adds information about electronic

records backup with the identification of storage location and validation of the storage system.

ANVISA (Brazil): ANVISA Resolution – RDC n. 17

ANVISA Resolution – RDC n. 17 was published on April 16, 2010. It is called the Technical Regulation of Good Manufacturing Practices of Drugs. The guidance provides details about computerized systems used in manufacturing, holding, packing and shipping of finished products. Computer system validation requires documented evidence that attests to a high degree of safety; analysis of a computerized system, controls, and records is performed correctly, and that data processing complies with predetermined specifications.

The Technical Regulation of Good Manufacturing Practices of Drugs per the ANVISA Resolution says the following (Article 223): during the production process, all steps undertaken should be recorded, looking at the initial time and final implementation of each operation. The record of implementation of these steps must be properly dated by the executors, clearly identified by signature or electronic password, and ratified by the area supervisor.

PFSB/ELD Notification No. 0401022 of Japan

In Japan, the Guideline on Control of Computerized Systems in Drug Manufacturing Regulatory Guide provides several requirements. These include guidelines for electromagnetic records and electronic signatures used for documents and source documents relevant to applications, notifications and reports for approval or licensing of drugs, quasi-drugs, cosmetics and medical devices, and registrations of conformity assessment bodies.

PHARMACEUTICAL CGMPS: A RISK-BASED APPROACH

Global regulatory agencies like the FDA have enhanced the regulation of pharmaceutical manufacturing and product quality by applying a scientific and risk-based approach to product quality regulation. This initiative incorporates an integrated quality-systems approach to current good manufacturing practice (cGMP). Regulatory agencies have 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 recent initiatives of global regulatory agencies.

Ultimately, your company must comply with applicable rules. Records that agencies require to be maintained or submitted must remain secure and reliable in accordance with the predicate rules. In an agency inspection, the inspection of any computerized system includes a review of the system documentation. The documentation is required to demonstrate that the regulated activities controlled by a computerized system can be reliably performed and reliably repeated as the user intends and as detailed by the system specifications. Regulated records must have the ability to be written to media and recovered without corrupting the original data, and audit trails must document the computer's action related to any changes to the data.

As with any regulated processes, computer processes are required to show documented validation, and any changes to the system must be tested and documented through a change control process. This testing needs to be rigorous and designed to "stress" the system. Documented training of personnel who were involved with system development, validation, deployment and maintenance is the basic premise of all regulated activities. This is exactly what the Life Sciences industry does for all processes.

OTHER INTERNATIONAL GMP GUIDELINES

Several other guidelines for good manufacturing practice include ERES regulations.

PIC/S Guidance

The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme (jointly referred to as PIC/S) published guidance called Guide to Good Manufacturing Practice for Medicinal Products, Annex 11 Computerized Systems in January 2013. The guidance provides background information and recommendations regarding inspection of and training concerning computerized systems. It contains a section on electronic records and signatures aligned to EU GMP expectations.

ICH Guideline

The International Conference on Harmonization (ICH) guideline, ICH Q7A, Part II Basic Requirements for Active Substances Used as Starting Materials, is the first GMP guideline that has been harmonized for the United States, the EU and Japan. ICH Q7A was published as Annex 18 in EU GMP Guidelines in July 2001. In addition, ICH Q7A has been adopted by Australia, Japan and PIC/S.

Chinese State Food and Drug Administration

The Ministry of Health in China adopted the Good Manufacturing Practice for Drugs on October 19, 2010. It was retroactive to March 1, 2010. This decree states that manufacturing and quality management of drugs shall be per GMP. Manufacturers must establish a quality management system covering all factors that influence quality of drugs. GMP must be strictly implemented with integrity. Any falsification and fraud is forbidden.

3. FUNCTIONALITY IN BEAS MANUFACTURING THAT MAY BE REGULATED

The determination of whether a transaction performed in Beas Manufacturing has regulatory compliance implications is directly dependent on the business process that is making use of the transaction. Creating a purchase order for sodium chloride to be used for melting ice and snow is drastically different than creating a purchase order for sodium chloride to use in your manufacturing process. The business processes and the subsequent records requirements for materials used in the manufacturing process are subject to the predicate rules associated with the cGMP.

The business process that your company uses to perform operations must comply with applicable FDA regulations governing **good clinical practice, good manufacturing practice, good laboratory practice and good deployment practice**, together referred to as GxP. These regulations require that you retain certain records and documentation to support these activities and demonstrate compliance. When your company uses a computerized system to support execution of all or part of your business processes, and that system creates, modifies, maintains or transmits records, those records are subject to regulatory requirements. And you need system controls to protect the accuracy, completeness, authenticity and reliability of those records.

Beas Manufacturing is a transaction-based software system. These transactions, when mapped to the business process flows that they use for execution, can be assessed for regulatory relevance. By identifying the tenets of the applicable regulations and attributing them to the corresponding steps of the business process, you can determine the regulated Beas Manufacturing application transactions. The following areas have consistently been shown to be relevant to regulatory issues.

Logistics include:

- Materials management

- Plant maintenance
- Production planning
- Production planning for process industries
- Quality management
- Sales and distribution
- Logistics execution
- Environment, health, and safety
- Human resources and training information
- Warehouse management

Central functions include:

- Batch management
- Handling unit management
- Document management

Cross-application components include:

- Engineering change management
- Classification
- Document management
- Electronic records (audit trail)
- Digital signature
- Notifications
- Records and case management
- Master data governance

Functional areas that have consistently been demonstrated **to be excluded from the FDA scope** are **finance** (financial accounting, controlling, and asset management components) and **planning** (demand management, forecasting, profitability analysis, and sales and operations planning components).
Assessing the applicability of regulations allows for testing that the electronic record requirements – and, if applicable, the electronic signature requirements – associated with the records created, modified, or maintained by these transactions are compliant with regulatory requirements. Conversely, if the assessment cannot identify a specific regulatory tenet, the records associated with that transaction code are not considered to be relevant to regulatory issues and therefore are not subject to the same regulatory records requirements.
Your Life Sciences company can dramatically reduce validation costs by performing this assessment and using the results during implementation projects. You can realize additional benefits during the production use of the system when you introduce changes to processes and functionality through change control.

ELECTRONIC RECORDS

In general, global regulatory agencies define an electronic record as follows:
Information created, stored, generated, received or communicated by electronic means in a form that a person can perceive and that can be accurately reproduced or distributed by a computer system.
If you apply this comprehensive definition to Beas Manufacturing, you find various types of electronic records, such

as:

- Configuration within the implementation guide
- Transports and business configuration sets used to migrate configuration from one software 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
- Electronic records for business processes or transaction execution, such as material documents
- Electronic or digital signatures

Table Logging

Where change masters or change document objects do not exist for a certain business document, you need an alternative method to maintain an audit trail.
The database table captures every dataset before the changes are made to this table and writes this information in a unique record. Any transaction executed within Beas Manufacturing includes multiple tables where the data is recorded and maintained. Therefore, to view the complete audit trail, you can run a report to query and display each record associated with a specific event.
Table logging may affect system performance, depending on the number of records that are generated. However, table logging is required only in some instances. You should review system configuration when table logging requirements have been identified.

Audit Trail

The audit trail (logging) component enables you to log and evaluate changed data in the system. The audit trail facilitates a detailed, consistent, and traceable description of your changes on field-level. You can change logging settings intuitively and without technical modification and carry out an evaluation of the changed data that conforms to FDA requirements.

Date and Time Stamp

Beas Manufacturing uses the time zone where the system is installed for change master record, change document objects, and table-logging activities. The time zone is unique and unequivocal.
To compare the local times of users in different time zones, SAP Business One represents times differently, externally and internally. External representation of time corresponds to a context-dependent local time. For example, time is represented in Germany in Central European Time and in New York in Eastern Standard Time. SAP Business One normalizes the internal system time to the time zone where installed, which serves as reference time. These procedures should be included in performance qualification testing.

ELECTRONIC SIGNATURE

Many agencies such as the FDA and EU authorities consider electronic records equivalent to paper records and electronic signatures equivalent to traditional handwritten signatures. For the FDA, the ERES guidance documents specify that these requirements are defined by the “predicate rule,” such as cGMP for finished pharmaceuticals (21 CFR Part 211) and medical devices (21 CFR Part 820). Note that some passages implicitly call for signatures, for example, wherever the words “approved,” “signed,” “initialed,” “authorized,” “rejected,” or “verified” are used.

Electronic and Digital Signatures in Beas Manufacturing

Electronic and digital signature definitions are shown in 21 CFR Part 11 as follows:

- Electronic signature – 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 – An electronic signature based on 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 – An environment in which system access is controlled by people who are responsible for the content of electronic records that are on the system
- Open system – An environment in which the system's access is not controlled by people who are responsible for the content of electronic records that are on the system

To ensure the integrity of signatures within an electronic system and protect them against falsification and data corruption, the FDA requires that the system actively detects and prevents unauthorized access. This includes reporting these attempts to the system's security unit. Many agencies equate the reporting and response of unauthorized access to the way "individuals would respond to a fire alarm," as mentioned in the Part 11 rule.

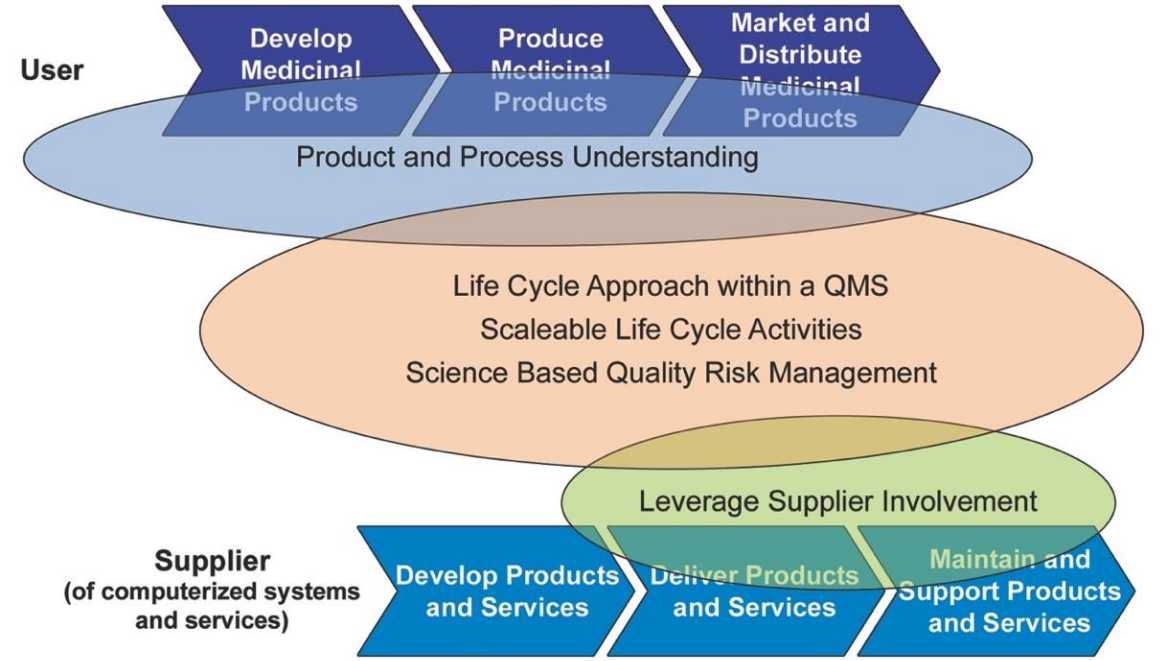
4. BOYUM SOFTWARE QUALITY

Beas quality control, release and support process of patch levels – synchronized with SAP

The continuous development of Beas Manufacturing – its commit in concept, development, testing and release – has called for meticulous compliance with high quality standards. For this purpose, a comprehensive quality management system has been established to control the new versions of Beas Manufacturing.
This QM system also includes change management as well as troubleshooting and support of its solutions. In this way, the entire system is covering the whole lifecycle.
For partners, all is backed by a workflow-driven ticket system, where all changes and support calls are documented. About sophisticated checklists, these tickets are evaluated and processed according to precise specifications. All steps taken are well documented and are traceable at any time.
In the end, each change or support request is subjected to a precise QC check and the QC manager passes it for delivery.
The QC check also includes extensive cross-function tests in which the effects on associated functions are checked. Every single ticket is also examined for CAPA impact. It checks which occurred errors can be avoided in the future in other areas. This leads to a continuous improvement of the overall system.

5. GOOD PRACTICE FOR THE SUPPLIER

Although the responsibility of compliance with the GMP regulations lies with regulated companies, the supplier may be highly involved in the process. Regulated companies want suppliers to use knowledge and documentation effectively, depending on their suitability and after a formal examination. Depending on the risk, complexity and novelty formal examination may include an audit.



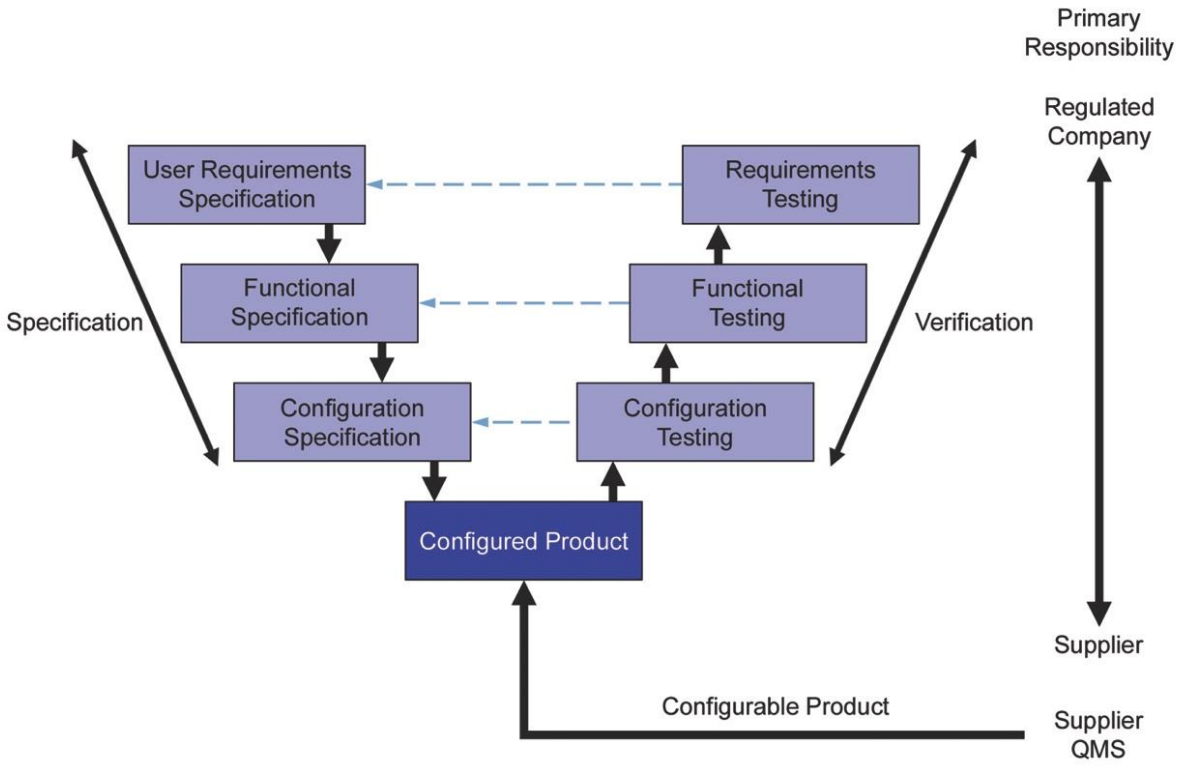
Source: Figure 2.1, GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems, © Copyright ISPE 2008. All rights reserved. www.ISPE.org.

GAMP5 – Software Category 4 (Configured Product)

If the product to support the specific business process needs to be specifically configured, the supplier involvement for the regulated company usually includes assistance in the specification, the configuration, verification and operation of the system. The procedures to follow should be agreed between the regulated companies and the supplier and will be documented in a suitable plan. Applied procedures can be derived from the QMS of the regulated company or the supplier. Suppliers providing services should operate within a QMS. The quality plan should specify the activities that approaches for the work to be performed and the responsibilities for the provision and monitoring of services. Such a plan is a contractual document and should be approved as such, for use both by the supplier and by the regulated company.

6. VALIDATION APPROACH TO ACHIEVE COMPLIANCE

Global agencies such as the FDA and EU authorities acknowledge the complexity and controversy of validating commercial software. The agencies reiterate the general principle of validation for which planned and expected performance is based on predetermined design specifications. The next sections discuss the validation requirements inferred in the regulations. Key activities necessary to validate Beas Manufacturing in compliance with ERES are as follows:



Source: Figure 4.3, GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems, © Copyright ISPE 2008. All rights reserved. www.ISPE.org.

➔ **Conduct system compliance assessment:**

- Evaluation of GxP predicate rules: Determine whether the computerized system is regulated by any GxP predicate rules
- Criticality assessment: Determine criticality of the computerized system based on the processes and the data those processes manage or support
- Complexity assessment: Determine the complexity of the computerized system based on technology, resources, software, and infrastructure requirements
- Determination of validation level: Determine the level of validation for the computerized system by the results of the previous compliance evaluation and assessments
- Identification of software category (such as GAMP 5.0)
- Deliverables determination: Validate deliverables based on your organization's internal requirements and the assessment results

➔ **Defining Part 11 requirements in:**

- User requirements
- Business process documents
- Functional design specification

➔ **Defining the overall strategy in the validation master plan and determine how the system will be deployed as per your software development lifecycle (SDLC) methodology.**

➔ **Conducting good practice assessments at the business process level:**

- Determine GxP-relevant business processes and Beas Manufacturing software objects
- Determine GxP relevance at the transaction, object, or field level

➔ **Developing security authorizations according to SDLC. Establish functional requirement specifications for business roles:**

- Use the business process master list as the only source of authorization profile development (this helps ensure that unused, non-validated tools to support business processes within Beas Manufacturing are effectively blocked from unauthorized access)
- Manage profiles similarly to configuration regarding change control and the transportation management component

➔ **Configuring software to activate complete audit trail reporting and electronic signatures.**

➔ **Testing the system:**

- Conduct formal testing of ERES requirements based on risk assessment results
- Create test objectives to demonstrate ERES compliance for each relevant clause of the regulation (for example, challenge the creation of an accurate and complete electronic record)
- Include negative testing of business-critical transactions (for example, cGMP) in system testing of profiles (see Appendix 3 for a suggested list of cGMP-critical transactions)

➔ **Training users for all transactions within their profiles.**

It is important to recognize the impact of ERES regulations interpretation – specifically, the word "complete" as it pertains to electronic records generated in Beas Manufacturing. To identify where ERES regulations apply, perform a GxP assessment. Before conducting this assessment, however, establish a strategy to define at what level the relevance to GxP will be assigned. For example, define the relevance at the transaction or object level (such as process order, material master, etc.) or at the field level (such as order quantity but not scheduling margin key for process order). This strategy is directly related to how the term "complete" is interpreted. You determine whether it is interpreted as all the data contained within the transaction or object itself or as only the data determined to be GxP relevant. It is important to understand the impact of each approach from both a compliance and a 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 at that level 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 Beas Manufacturing can be scrutinized – potentially invoking challenge field by field within transactions and master data objects. You need additional written justification to clearly explain the assessment of why certain fields are not GxP relevant. This approach can also be challenged with the technical argument that the integration of Beas Manufacturing software infrastructure maintains both GxP and non-GxP data within the same database tables and business processes. Therefore, all data within these tables and transactions is subject to the same level of control to protect the integrity of the GxP data.

7. WHY CHOOSE BEAS MANUFACTURING FOR COMPLIANCE

BOYUM SOLUTIONS EXPERIENCE AND SAP EXPERTISE CREATE COMPETITIVE ADVANTAGES

Boyum is offering specific manufacturing industry solutions developed 100 percent based on SAP technologies and tailored for SAP Business One. So SME sectors and subsidiaries from large enterprises are able to use manufacturing industry application solutions to fit their market's needs.

The supported business processes are:

- Make-to-stock, make-to-order, engineer-to-order / projects
- Assembly / configure-to-order / variant production
- Supply chain management process integration
- All mixed-mode types

BENEFITS OF BEAS MANUFACTURING

- Above-average functional industry coverage and process support
- Quick, effortless and cost-effective implementation. Industry specifics are considered, integrated and available from the very outset.
- Best-practice process, including options for easily and flexibly modifying or adding integrated business scenarios to meet your individual business requirements/typologies across all process chains.
- Transparent process analyses ("inside views") support companies in continuously reviewing the effects of optimization projects (such as lean manufacturing, improving product margins, etc.) using defined KPIs
- Use and integration of the latest technologies and innovations, from SAP ERP certified integrations to SAP HANA and analysis applications, as well as SAP cloud and mobile solutions.

Some of the industry-specific benefits of Beas Manufacturing for Life Sciences or Personal Care:

- Considers legal standards and GMP guidelines (FDA, EMA, BRC, IFRA, GHS etc.) in accordance with industry-specific requirements
- Integration of complex formulation, compliance checks and document creation
- Quality assurance through complete documentation of data modifications, production and quality control data, including all testing, approval and release steps (two-man rule, electronic signature)
- Easy-to-use cost calculation and cost accounting with profit and loss calculations for each product line, multi-level margin calculation, etc.
- Seamless integration of subsystems like SCADA, LIMS, etc.

Some of the industry-specific benefits of Beas Manufacturing for Medical Devices & Components:

- ISO compliance (functional) through
  - Quality assurance all along the supply chain
  - Comprehensive documentation (version, revision, drawing, batch and serial numbers)
- Project cockpit for trackable SCM: from engineering and prototyping via production to customer acceptance, budget and cost controlling
- APS (Advanced Planning and Scheduling) for groups, individual and alternative resources (machinery, tools, personnel), in order to optimize capacity and productivity
- Easy integration of subsystems like CAD/PLM, machinery (PLC), pattern optimization, etc.

BEST PRACTICE

Important: the Beas configuration wizard allows users to enable/disable Beas modules (functional width and depth) as well as to set up various best practice business scenarios (workflows) which give you the reliability to be able to optimize and scale your IT solution for your business at any time.
Beas does not only serve your business processes – it also provides the 'inside view' to monitor continuous improvement (e.g. lean manufacturing projects) or the impact of changes (e.g. margin improvements of product groups) based on all definable KPIs.

Bibliography

European Commission (2011):

EudraLex

The Rules Governing Medicinal Products in the European Union - Volume 4

Good Manufacturing Practice: Medicinal Products for Human and Veterinary Use – **Annex 11: Computerised Systems**

ISPE (2008):

GAMP 5: A risk-Based Approach to Compliant Computerized Systems

U.S. Department Of Health and Human Services (2002):

General Principles of Software Validation; Final Guidance for Industry and FDA Staff

SAP AG (2013):

Complying with Global ERES Regulations in the Life Science Industry