



Life Sciences Capability Document

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EC Manage Service Offerings for the Life Sciences Industries

Life Sciences

The goal of every organization within the life sciences, pharmaceutical and healthcare domain, from discovery through manufacturing, is to reduce time-to-market at the same time be compliant with the FDA regulations (GxP, 21 CFR Part11 etc.) By implementing new processes and technologies, businesses can achieve both objectives and at the same time reduce cost. Technology is playing a very important role in achieving these business objectives. Technology has become integral part critical business functions such as of clinical development (labs and manufacturing automation), supply chain and manufacturing. It is not only used in day-to-day operations in labs (data collection, management and archiving) and manufacturing, but also to build up a competitive advantage (DW/BI, Knowledge Management).

EC Manage Offerings

EC Manage helps life science and pharmaceutical companies reduce “Time-to-market” by offering solutions and services such as system implementation (development and/or integration), system validation, and project management in areas like:

- Laboratory Data Management (LIMS, Long term Archiving, eNoteBook)
- Regulatory Compliance
- Clinical and Supply Chain Data Integration
- Knowledge Management
- Supply Chain Management

Laboratory Data Management

EC Manage has expertise in integrating laboratory systems utilizing a variety of tools and custom interfaces. We help you maximize your investments by integrating your laboratory information management systems (LIMS), scientific data acquisition systems, long-term archiving systems, and electronic laboratory notebooks.

At EC Manage, we offer our expertise and capabilities either in new implementation initiatives or for upgrades or customizations of existing systems. We offer services at any phase of a project, from assessment until the final production rollout. Our proprietary system implementation and project management methodology helps us implement quality driven systems keeping your business goals in mind.

Regulatory Compliance

Regulatory compliance is a key factor determining success in the pharmaceutical industry. Since companies are regulated by FDA, it is critical that the technologies used for supporting business processes must be compliant with FDA regulations such as GxP and 21 CFR Part 11.

Implementation of a validated system typically adds 25% to 50% to total system cost. Companies must develop cost-effective strategies and relationships with experienced validation partners to achieve efficiencies that will as a result mitigate cost.

EC Manage services can help organizations like yours with cost-effective solutions to implement processes and technologies to mitigate risk of non-compliance.

We Offer Services in

- Compliance focused GAP analysis and recommendations
- Technology assessment and evaluation
- Implementation of custom and commercial off the shelf (COTS) IT systems
- Infrastructure qualification (networks, servers, computer room environments)
- Creation of computer system validation policies and procedures
- Management consulting services that establish a risk-based approach to validation
- Development of standard templates for validation documents
- IQ/OQ/PQ planning, development, and execution
- Delivery of validation life-cycle training tailored to client corporate polices
- IT assessments that focus on the complete IT integration

Clinical and Supply Chain Integration

Most of the pharmaceutical and Biotech companies use multiple Clinical Research Organizations (CROs) for clinical trial management. Due to lack of advanced technology in the third world countries, IVR systems are used to manage dispensing drugs to patients. Every clinical trial is custom developed and validated hence results in loss of time and productivity. Most of the time CROs and their clients work in silos. Data exchange is done either manually or via email thus resulting in redundancy.

Companies can achieve significant ROI in terms of increase in productivity and reduction in time if they integrate their internal applications (such as trial management, clinical data management, and supply chain) with CRO applications.

At EC Manage, we offer XML based open architecture that standardizes the data communication between the internal and external systems and hence reduces the clinical study setup, increasing the productivity and ensuring data reliability.

Significant Benefits Include

- Efficient trial management by standardized initiation and ongoing activities
- Closer partnership with investigative sites
- Reduction in manual manipulation of data by seamless real-time electronic data exchange
- Standardized user training resulting into reduction of learning curve
- Potential time saving of 5-8 weeks in IVRS study set up by using template based simple and standardized development and validation process
- Real-time inventory dashboard for investigation sites

Knowledge Management

Providing the “right information to right people at right time” is very critical for decision-making. Many business critical decisions and strategies fail due to lack of facts (historical data) or not getting the information required at right time.

Today, Knowledge Management with help of technologies such as Data Warehousing (DW) and Business Intelligence (BI), Content Management could play a crucial role in making right decisions in time thus reducing waste (in money and time) and generating a competitive edge.

Although the knowledge management initiative is corporate-wide, you can implement knowledge management for smaller business units or departments. These smaller knowledge management systems have helped lower costs, improved productivity and achieved regulatory compliance for departments such as R&D, manufacturing, sales and marketing.

Motivation

- Pharmaceutical industry is deluged with glut of information
- Every minute scientific knowledge increases by 2,000 pages
- Every day we send the equivalent of more than 300 million pages of text over the Internet
- It takes five years to read the new scientific material produced every 24 hours
- Over half of all scientific knowledge becomes outdated every ten years
- Inefficiencies in searching and retrieving data
- Issues related to information sharing and management of knowledge assets
- Process efficiencies result in cost benefits
 - Up to US\$264 million in R&D per drug
- Competitive edge due to better utilization of data and shortened time to market
 - Savings of up to one year per drug
 - For a US\$1 billion drug delay of one day equivalent to loss of US\$ 2.5 million in sales
- People inefficiency leading to loss in productivity
 - Scientists and decision makers spend time searching for information
 - Scientists and decision makers spend time verifying whether the information is current and validated
- Organization inefficiency
 - Lack of real time integration results in delay of information flow leading to delay in decision making

EC Manage has proven expertise and recommendations in implementing cost-effective, technology-driven knowledge management solutions from collaboration, to document management, to workflow, to e-learning solutions, to knowledge sharing.

Supply Chain Management

An integrated supply chain management streamlines processes and increases profitability by delivering the right product to the right place, at the right time, and at lowest possible cost. Unlike commercial manufacturing supplies, clinical supplies' planning is very dynamic and can often have last minute change. Availability of patient kit when patient arrives at investigator site is very important for clinical trial success. This results into overproduction of drug products to take care of last minute change in demand. R&D manufacturing is very expensive and overproduction of patient kits adds significant cost to the total cost of clinical trials.

An integrated supply chain can reduce the overproduction of drug products by efficient demand management, planning, and inventory management. Implementation of ERP system (such as SAP) in R&D can have major ROI by reducing the overproduction and efficient supply and EC Manage has proven expertise and recommendations in inventory management. implementing cost-effective, technology-driven knowledge management solutions from collaboration, to document management, to workflow, to e-learning solutions, to knowledge sharing.

EC Manage' Life Sciences Capabilities

Life sciences involves industries like pharmaceutical, biotech and medical devices which involves lot of critical process both online and offline. It has been a challenge for the industry experts to figure out a proper solution for their problems and pain areas like

- Pressures on pipeline and productivity in research and development.
- Changing regulatory burdens
- Counterfeit products and patent expirations
- Timeline erosion from drug discovery through clinical trials to regulatory approvals

We leverage the strengths & Life sciences advantages of SAP to address this critical concerns of the industry.

- Streamline business processes from end-to-end
- Integrate ERP to your business processes
- The most for your money

Industry Benefits

- Increased revenue – Life Sciences solutions provide real-time visibility into product performance – enabling companies to speed time to market and realize a greater return.
- Reduced costs – Life Sciences offers a full suite of enterprise management solutions that facilitates the implementation and maintenance of system interfaces, resulting in reduced IT costs and lower TCO.
- Mitigated risk – Life Sciences solutions, we can leverage proven tools – and SAP's 30-year track record as a qualified supplier to hundreds of life sciences companies – to meet GxP, PDMA, Sarbanes-Oxley, and 21 CFR Part 11 requirements, and simplify computer system validation.
- Improved product quality – Life Sciences, critical quality control and quality assurance processes become seamless and visible – allowing us to proactively manage manufacturing variability, track product quality, and take exceptional corrective action or preventive action (CAPA).

Industry Wide Solutions for Life Sciences

Pharmaceuticals

Industry wise R&D investments, actively manage product safety, improve product quality, mitigate risk of non-compliance, accelerate regulatory submissions, meet validation requirements, decrease time to peak sales, and improve contract management.

Solutions for Pharmaceutical Companies

Managing the business of a growing pharmaceutical company involves significant challenges. To be successful, companies need to have cost-effective R&D; procure, manage, and enable a high quality workforce; and achieve new levels of operational excellence, while managing the strictest adherence to government regulations. We provide the necessary business process end to end.

Life Sciences solutions for the pharmaceutical industry can help organization manage R&D projects efficiently, supporting the capture of documentation, and enabling collaboration among researchers. We can enable quicker and more cost efficient clinical trials by ensuring that the organization has an effective clinical trial supply chain by providing prompt packaging, labeling and shipment to different sales locations.

As the retaining and utilizing of the workforce is as difficult as attracting the talented workforce, many pharmaceutical companies use SAP's human capital management (HCM) solutions. SAP's HCM capabilities enable an organization to recruit more effectively, align people around common corporate goals, enable learning, and more.

As in R&D, the conjunction of great information and collaboration tools, together with a great workforce, drives operational results. In every sect from procurement through manufacturing and shipping, warehousing, logistics, and order management, the SAP ERP and SAP Supply Chain Management (SAP SCM) applications enable efficiency, quality, and customer responsiveness. SAP solutions enable and

provide simultaneous compliances with a myriad of regulations, including Sarbanes-Oxley act, 21 CFR part 11, U.S. Health Insurance Portability and Accountability Act (HIPPA), GxPs, and regulations imposed by the FDA, DEA, EPA, and other agencies. Hence we take advantage of these benefits to our customers.

Biotechnology and Biopharmaceuticals

Identify products with the best market opportunities, recognize product pipeline gaps, find better leads faster, and add proven strategic infrastructure to better manage and support compliance and scale-up for organic growth.

Solutions for Biotechnology and Biopharmaceutical Companies

Leveraging SAP solutions, we provide biotechnology companies with developing treatments to creating diagnostic and research materials. Using SAP solutions, companies are finding better leads faster, recognizing product pipeline gaps, and adding proven strategic infrastructure to better manage and support compliance, attract top-tier business partners, and scale-up for organic growth.

SAP solutions helps EC Manage address a variety of business challenges, such as:

- Supporting more effective R&D and clinical trials
- Sustaining profitable growth and operational excellence
- Responding to changes in the healthcare industry and standards of care
- Managing compliance in an increasingly complex regulatory environment
- Providing business transparency and credibility to private and public investors

Medical Devices and Scientific Instruments

By integrating data across divisions and applications, we provide improved product quality, speed time to market, manage compliance, cut costs, and improve operating margins, streamlining business processes, gaining visibility across R&D and manufacturing, effectively managing field resources, and delivering excellence in customer service.

Solutions for Medical Device and Scientific Instrument Manufacturers

The lifeline for the development of a new product of any medical device company has never been faster. Medical device manufacturers face dynamic challenges on many fronts. Regulatory requirements from government agencies worldwide continue to grow in number and complexity, as do reimbursement policies and legislative demands. On top of it all, competition is relentless, with companies that drop behind in the aggressively competitive race-to-market positioned for acquisition.

To succeed in this industry, companies need cost-effective, information management solutions that enable them to make better decisions and rapidly respond to the industry's specialized challenges and growth opportunities – solutions that can only come from a partner with deep industry experience.

Solutions From SAP That We Leverage Upon

SAP for Life Sciences solutions provide medical device companies with an end-to-end, industry-specific means to support all business processes – from procurement and supply chain management, through manufacturing, customer, and order management. More than just enterprise resource planning supply chain management, and customer relationship management solutions

- Provide better visibility into operations through the ability to monitor, manage, and analyze integrated information from across the enterprise.
- Reduce compliance risk through proven GXP, 21CFR Part 11, audit trail, and EBR compliance technology, the ability to apply electronic signatures at all levels, and ease of validation.
- Achieve lowest total cost of ownership through proven implementation methodologies in validated environments; fewer costly and complex interfaces; the use of an open, cross-enterprise application and integration platform; and simplified maintenance.

Business Processes in Life Sciences

- Enterprise Management
- Product Development
- Supply Chain Management
- Manufacturing
- Sales and Service

Life Sciences Business Scenarios

Research

- 1) Intellectual Property and Patent Management.

Drug discovery begins with research on compounds, taking thru screening process for milestones like targets, hits, leads based on probability of success using various IT systems involving simulation / informatics etc. These ideas and concepts are captured as part of company's corporate Intellectual Property (IP) portfolio which lies at the foundation of any successful life science research and development. Firms ranging in size from small startups to large life sciences companies seek the most effective ways to procure, patent, and generally protect their intellectual portfolios.

- a) Idea and Concept Management.
- b) Intellectual Property
- c) Patent Management

2) Alliance Management

The Alliance Management scenario focuses on supporting the alliances that are becoming an increasingly crucial part of the biopharma landscape, thus requiring solutions that ensure alliances between two companies are kept on track to deliver value to both parties. The process of internal assessment of Drug Discovery opportunities and the subsequent alliances, range from technology to marketed-product-based collaborations that lead to in- and out- licensing agreements that take advantage of synergies between partners.

- a) Co-Licensing Agreement
- b) Collaboration

Design & Development

1) R&D Administration:

R&D Administration encompasses enterprise wide project and portfolio management to ensure an optimized use of the R&D investment and resources. It ranges from planning and forecasting, over budgeting and cost controlling to resource and capacity management. It delivers timely and accurate data for decision support, aligns project performance with company goals and increases the efficiency of the development process.

- a) Portfolio Management.
- b) Program Management.
- c) Project Planning.
- d) Capacity Management.
- e) Project Execution.
- f) Project Accounting.
- g) Reporting & Analysis.

2) Process & Product life cycle management.

Managing development operations through-out the life-cycle of the product which is a drug or a medical device and focusing on the process to develop that product from R&D to Commercialization

- a) Pharma/bio/ Chemical Development.
- b) Process Engineering.
- c) Document management & Change management.
- d) Prototyping & Ramp up

3) Clinical trial management.

Clinical Trial Management focuses on a smooth study cycle, which involves finding enough patients and investigators. It involves study design, initiation, and training for investigators, auditing sites and monitoring the study process. Besides the pure Clinical Trial Management, data management also needs to be considered. Patient data is collected electronically or on paper and will undergo vigorous quality checks, before it is statistically analyzed and used as a basis of the regulatory submission.

- a) Study definition & design.
- b) Patient Recruitment & Enrollment.
- c) Investigator Relation management.
- d) Clinical Relationship Management.
- e) Clinical trial management.
- f) Clinical trial collaboration
- g) Clinical data management.

4) Clinical trial supply management:

Clinical Trial Supply Management is focused on clinical trial material production, labeling, packaging and replenishment to ensure on time and correct delivery to sites. Visibility of the supply chain from raw materials to final delivery is key for accurate planning and forecasting. CTSM supports flexible manufacturing strategies and helps study sponsors manage their process in-house or with their business partners (e.g. contract manufacturers or CROs)

- a) Planning & Forecasting.
- b) Purchasing.
- c) Manufacturing & Labeling
- d) Clinical Supply Inventory.
- e) Patient kit replenishment.
- f) Distribution
- g) Drug Accountability

Product Supply

Procure to pay:

Procure to Pay is the process of obtaining and managing all raw materials needed for manufacturing. This cycle starts with the source selection, auditing followed by procurement of goods and services. The contracts with the suppliers are managed and can also include supplier managed inventories or direct inventory visibility. It also comprises direct procurement requirements through conversion from demands to purchase orders and confirmation of goods receipt. The incoming materials are then inspected and posted into inventory as part of managing the warehouse. The last activity in this cycle is payment of the suppliers which consists of receiving, entering and checking vendor's invoice for correctness.

- a) Strategic sourcing
- b) Supplier collaboration
- c) Procurement.
- d) Receiving and inspection.
- e) Inventory management.
- f) Reporting.

1) Supply chain planning:

Supply Planning covers optimization of supply and demand while Production Planning & Detailed Scheduling supports the process of assigning production orders to resources in a specific sequence and time-frame. Forecast, derived from historical and other sources of data, and demand, based on received orders and inventory levels can be planned. Unexpected changes can be managed in order to meet changing customer or supplier situations. Through the integration of planning with manufacturing the capacity utilization of all assets can be optimized.

- a) Forecasting and demand planning
- b) Supply planning
- c) Production planning.
- d) Detailed Scheduling.

2) Compliant Manufacturing:

Compliant Manufacturing enables customers to enforce compliance throughout their manufacturing process. This process supports multiple manufacturing strategies like make-to-stock, make-to-order etc and also covers various types of manufacturing process like in-house or out-sourced manufacturing

- a) Process manufacturing.
- b) Contract Manufacturing.
- c) Lean manufacturing.
- d) Manufacturing Performance Management.

3) Enterprise LIMS :

Laboratory Information Management Systems (LIMS) are software-based systems that automate the work processes and tedious administrative functions of a laboratory in R&D and manufacturing. LIMS manages the complete test routine including sample log-in, testing, re-

testing and final reports. LIMS also includes functions such as stability studies; sample management; inspection plan and test equipment calibration. Enterprise LIMS extends that functionality through the integration to company-wide resource planning systems to include lab management, work scheduling, and product release as well as trending and analytics.

- a) Laboratory management.
- b) Inspection plan & Sample management.
- c) Stability studies.
- d) Inspection Results and Lot disposition.
- e) Reporting.

4) Equipment Maintenance:

Equipment Maintenance describes the capabilities necessary for a compliant, fully-integrated, maintenance management system. This includes work scheduling, integrated procurement for maintenance supplies, inventory management and shutdown planning in a web based or mobile solution. Maintenance execution supports problem handling, capacity and requirements planning, spare parts planning, and budgeting. The information from machinery can be collected and automatic status changes can be performed, e.g. upon run time or alerts. The calibration of manufacturing equipment, tools, and gauges further supplements Compliant Manufacturing.

- a) Equipment management.
- b) Maintenance Execution
- c) Test Equipment Calibration.
- d) Reporting.

5) Warehouse management

SAP Supply Chain Management includes comprehensive support of warehousing and shipping processes. This covers the entire material flow from receiving through storing and shipping materials. Cross-docking, handling of packing and packages, yard management as well as advanced warehouse management strategies for picking and receiving accelerate the supply chain and raise efficiencies.

- a) Inbound and out bound logistics.
- b) Cross docking.
- c) Warehousing and Storage.
- d) Physical inventory.

6) Order 2 Cash:

As Pharmaceutical companies are faced with increasing cost pressures due to intensifying competition, one area of focus is increasing order fulfillment efficiency including improved cycle times and accuracy of shipments. This scenario covers the complete Order to Cash process providing faster processing of sales documents, more efficient deliveries, reduction in transportation costs including adhering to compliances requirements, and finally closing out the process with billing. Overall SAP's integrated solution gives users more transparency over the entire order to cash cycle

- a) Sales order management.
- b) Logistics Execution.
- c) Returns and Recall management.
- d) Transportation.
- e) Billing.

Sales & Manufacturing

1) Contract management:

The dynamics of today's economy are requiring pharmaceutical companies to rigorously manage costs and government compliance, as they aspire to increase market share with innovative sales strategies. To ensure profitable growth, companies are responding faster and more accurately to changing market demands, requiring well-defined and measurable goals. This is especially true in the area of sales contract development and pricing, chargeback and rebate management. To meet this complex challenge, a total, consistent, and integrated solution is essential. The business scenario Contract Management covers the main business processes of a pharmaceutical or medical supplies manufacturer for contract and chargeback claims management as well as managed care and government rebates. Tight integration into accounts receivable is provided through the dispute management process that allows efficient clarification of disputed invoices and deductions.

- a) Contract development.
- b) Charge back/Distributor rebates.
- c) Commercial rebate processing.
- d) Government Pricing & Medical Claims.
- e) Dispute Resolution.
- f) Contract Compliance.

2) Marketing:

With the ultimate goal of increasing brand awareness and driving company growth, the marketing scenario covers all processes related to promoting product sales. This scenario encompasses product management, campaign and customer event management as well as key account management. Based on all enterprise wide information sources (sales and delivery data, cost and price information) as well as external data a segmentation of the customer groups is done which is crucial to leverage the cost-intensive sales force and to overcome the current trend of declining sales force efficiency. By assigning the appropriate target group to the different channels (sales force, interaction center, and Internet) as a result of segmentation, all marketing and sales resources are managed to derive maximum sales impact. The consistent planning and execution of campaigns, promotions and events to all types of customers is the other centerpiece of marketing. Key Account Management finally covers all activities towards actual buyers (wholesalers etc.), payers (Formulary Management) and key opinion leaders.

- a) Customer Segmentation.
- b) Marketing Planning and Budgeting.
- c) Campaign management.
- d) Product management.
- e) Key account management.
- f) Brand management.
- g) Trade promotion management.

3) Field Sales:

The increasing number of pharmaceutical sales reps in the marketplace and more regulations around the interaction with physicians are among the key drivers for improved sales effectiveness. The Sales Reps follow a customer centric approach using an integrated, analytical driven solution to plan and document interactions with customers (physicians, pharmacists etc). As these activities are part of a streamlined process it allows to utilize multi-channel capabilities to increase share of voice to the relevant customers. The scenario also includes PDMA

compliant sample management as well as support for all administrative processes, which reduces the cost of selling.

- a) Account Processing.
- b) Activity Analysis.
- c) Activity management.
- d) Targeting and call management.
- e) Tour planning.
- f) Call execution and Reporting.
- g) Visit planning.
- h) Order capture.
- i) Time and Expense Reporting.

4) Sales Operations and Performance Analytics:

Sales Operations and Performance Analytics covers all back-office activities that support and manage the Field Sales Force. Full Sample Accountability is achieved by close integration with the Field Sales Scenario utilizing the integrated analytical, workflow and case management capabilities. The scenario also covers all analytical back office functions from high level planning down to prescriber level and longitudinal reporting, integrating multiple internal and external data sources, in order to gain full market insight into the prescriber and patient eco-system. Analytical capabilities also provide insight into sales performance, which allows implementing and monitoring a given sales strategy through incentives management and territory alignment.

- a) Customer data validation.
- b) Sales Strategy & Compensation.
- c) Sales planning & Reporting.
- d) Sales Service.
- e) Territory Assignment & Scheduling.
- f) Territory/ organizational mapping
- g) Interface to third party interface tool.

5) Channel management:

SAP CRM empowers organizations to manage partner relationships and enable channel partners (resellers, dealers, distributors, agents...) to sell more effectively – resulting in a more profitable indirect channel. Organizations can more effectively work with and leverage channel partners to better market to, sell to and service end customers.

- a) Channel partner qualification.
- b) Channel partner processing.
- c) Channel partner Quote to cash.
- d) Channel inventory management and reconciliation.
- e) Resale and Claim message processing.

EC Manage Support Services

1) Customer service management.

Customer Service is critical to the success of most businesses. Several components of Customer Service exist to support businesses in identifying, targeting and profitably exceeding their customers' expectations. Service Sales & Marketing enables companies to plan and execute marketing strategies and monitor their results for service related activities, which supports organizations in accurately planning and forecasting service sales activities, rapidly analyzing their service sales pipeline, effectively managing tasks, targeting cross-selling and up-selling opportunities, and promoting collaboration in a team-selling environment. This enables companies to plan and forecast services and the necessary resources (people, parts, tools). Most companies also provide service to customers through Interaction or Call Centers. Customers can contact our company through their preferred channels, including telephone, email, fax, letter and web chat. Interaction Center agents can record service requirements and provide updates on existing service requests with a full view of the customer's installations & assets, their complete service history, planned services and relevant recalls or service letters. On-site appointments for service technicians can be scheduled by the Interaction Center agents, even combining reactive service visits with existing preventive maintenance plans.

- a) Service planning.
- b) Service processing.
- c) Customer service and support.
- d) Self service support.
- e) Service support analysis.

2) Parts management:

Service parts planning enables the service parts network to forecast parts demand, derive optimal stocking levels for each location, plan parts replenishment, and rebalance the inventory within the network. The service parts planning process addresses specific needs such as slow- and fast-moving parts demand forecasting, parts life cycle planning, interchangeability / supersession of parts, and inventory planning for multiple hierarchies.

- a) Design.
- b) Parts planning.
- c) Parts monitoring.
- d) SC Collaboration & Reporting.

3) Service execution:

Service Execution helps service organizations efficiently manage and effectively use their service resources, which may include those in the field. They address the needs of OEMs who sell complex products that cannot be easily returned to service centers when they fail and require some level of technical expertise to install and repair, often at the customer's site. This also includes the support and use of mobile devices allowing field service technicians access to current and real time information. Some OEMs provide complex services, which are not limited to break/fix. Managing a network service or IT infrastructure requires professional support. This includes a comprehensive set of capabilities designed for professional services including the selling, estimating, planning, delivery, management, billing, and evaluation of project-based services

- a) Repair Processing.
- b) Order processing.
- c) Warranty management.
- d) Billing.
- e) Resource planning.

Compliance & Safety

1) Regulatory Submission:

The responsibility to ensure product safety and quality of drugs to their respective market is a key responsibility for regulatory agencies and a great impact on the industry. The need to gain approval or communicate to regulatory agencies throughout the product life-cycle becomes challenging as each country has their own requirements. Beginning with the content and source management, regulatory submissions must comply with the regulations that describe the structure and content of electronic or paper submission dossiers and additional communications

- a) Product Registration
- b) Content & Document Management
- c) Regulatory Agency Template Management
- d) Submission Compilation & Review
- e) Publishing
- f) Submission Life Cycle Management

1) Product Quality & CAPA

SAP Product Life cycle Management is a superior tool to support the product development process from the early stages down to the handover to production, sales, service and maintenance . The quality notification can be equally used for processing improvements of a company's own processes and products, and for processing complaints against suppliers as well as from customers.

- a) Quality control.
- b) Quality Assurance.
- c) Quality Engineering and Improvements

2) Product & Patient Safety:

Regulatory agencies in the Life Sciences industry are vigilant in assuring the safety of medical products at all stages in the product life-cycle - manufacturing, distribution and consumption or usage. Those companies that excel at proactively managing product safety continuously improve their product quality. The solutions help customers maintain one global system with consistent information regarding all complaints; gain visibility on the progress of investigations and increase speed of communication and issue resolution. Reporting and trend analysis on a global level allows companies to anticipate potential product safety issues by utilizing early warning signals to support corrective actions

- a) Medical Inquiries
- b) Complaint Management
- c) Adverse Events
- d) Reporting & Trending Analytics

4) Secure Tracking & Tracing

The goal of drug tracking and tracing is to prevent unsafe product from entering the supply chain by establishing a secure electronic pedigree so that every unit of medication is authenticated. The use of Electronic Product Code (EPC) technology allows individual product units to be tracked, traced and monitored using radio frequency identification (RFID). This technology can be used in conjunction with current business processes designed to track and trace product

- a) Outbound Processing
- b) Product Tracking & Authentication (PTA)

- c) Inbound processing
- d) Supply chain integration.

5) Risk Management

Life sciences organizations must deal with a broad range of industry-specific regulatory issues in addition to standard corporate governance, risk, and compliance demands. In fact, regulatory compliance is a core part of the business, ensuring a competitive supply chain, promoting customer confidence, and enabling profitable growth.

SAP solutions for governance, risk, and compliance (GRC) support the requirements of life sciences organizations to manage risk across the enterprise, increase business performance, and drive competitive advantage. Life sciences companies are specifically challenged to address risk across their core business areas that include: finance, operations, environment, and global trade. To meet these objectives and ensure corporate sustainability, SAP solutions for GRC unify corporate strategy, risk management, and control initiatives across the extended enterprise.

- a) Access and Authorization Control
- b) Process Control
- c) Risk Management

Quality Assurance & Management Best Practices for Life Sciences

The Quality Management component is part of the integrated R/3 System. The most important elements of a SAP Life Sciences Quality Management system are Quality planning that includes Preparation of Test Scenarios, Unit Testing, Integration Testing. Basic Data for Quality Management, Inspection planning. The Quality assurance deals with Quality inspection and notifications.

A detailed Creation of Inspection plan has to be created for Raw Material, In-Process. The Quality notifications, Quality certificates, Master Inspection characteristics, defect codes and task codes have to be defined. Stability study of all the true co-products have to be performed on a regular basis.

Monitors the shelf-life of batches and the deadline for recurring inspections. Carries out batch determination using characteristic values from quality inspections. Manages the inventory of goods during the inspection and takes the goods being inspected into account for materials planning purposes. Blocks payments until inspection lots are accepted. Transfers inspection results to batch characteristic values. Integrates inspection planning and work scheduling. Handles inspection characteristics and setup characteristics for operations. Manages quality inspections for manufacturing orders. Handles in-process inspections during production at freely defined inspection points.

Triggers final inspection upon goods receipt from production. Manages partial lots of a material during production that differs in quality and assigns partial lots to batches. Confirms quality and quantity information for manufacturing orders. Monitors production quality with the help of control charts and determines process capability scores. Manages problems in production using quality notifications and by processing corrective tasks. Manages customer-related quality information. Triggers an inspection at shipping when the delivery is created. Creates quality certificates with the delivery. Manages problems in sales & distribution with the help of quality notifications and by processing customer complaints. Settles appraisal and nonconformity costs.

The following is the process of Quality Management

- 1) Master Data maintenance
- 2) Process for Procurement
- 3) Process for In process inspection
- 4) Process for Sales & Distribution

EC Manage - Life Sciences

Business Scenarios Mapped with Technical and Functional Expertise

Business Scenario	SAP Function Module
Research	
Intellectual Property and Patent Management	
Alliance Management	
Design & Development	
R&D Administration	
Process & Product life cycle management	
Clinical trial management	
Clinical trial supply management	
Product Supply	
Procure to pay	MM and AP
Supply Chain Planning	APO
Compliant Manufacturing	PP
Enterprise LIMS	PP
Equipment Maintenance	PM
Warehouse Management	MM and WM
Order to Cash	SD and AR
Sales and Marketing	
Contract Management	SD
Marketing	SD
Field Sales	SD
Sales operations and performance analysis	SD
Channel Management	SD
Support Services	
Customer Service Management	CRM
Parts Management	MM
Service Execution	CRM

EC Manage Case Study One

SAP Life Sciences Implementation for Genentech

Abstract

A Global life sciences company wants to implement SAP solution to meet the increasingly sophisticated needs of the organization.

The Challenge

- The company had multiple legacy systems for their different facilities which is not helping them on improving their processes and meet the market demand on time.
- Huge transactional data resulting from multiple operational tickets.
- Challenge with scheduling plant maintenance and adherence to genealogy.

How we helped

- Designed the solution in such a way that transactional data is minimized yet improve the operational efficiency.
- Integrated multiple Legacy systems with SAP

Lessons Learned

- The client is now realizing the operational performance benefits gained from the system implementation.

EC Manage Case Study Two

SAP Life sciences implementation for Lannett

Abstract

Lannett company inc. is the oldest generic drug manufacturer in the United States. Over the past five years, the company has expanded from 70 to 170 employees while boosting revenues from \$10 million to \$70 million. To manage its explosive growth, lannett needed a platform based on industry best practices.

The Challenge

- Inability to manage growth due to lack of adequate IT support
- Price pressure
- Customer demand for value-added services
- Lack of transparent information and process control

- Increased regulatory compliance requirements

How we helped:

- Provided solid platform for growth
- Reduced reporting times
- Improved access to information
- Reduced cost of compliance through operational efficiencies

Lessons Learned

- The client is now realizing the operational and performance benefits gained from the system upgrade