Agenda

• External industry pressures
• How have Quality and Manufacturing responded?
• How does this impact SIRS®?
• Background and study process
• Typical organization structure
• Discussion and review of benchmark changes
• Appendix
EXTERNAL INDUSTRY PRESSURES
External Industry Pressures
Quality and Manufacturing Issues

• Compliance issues in Quality and Manufacturing
  – Plant shutdowns due to FDA inspection failures
  – Increasing adverse event reports
  – Decrease of consumer confidence in product lines and company brands
  – Decreased market share of individual companies resulting from production disruptions

• Cost constraints
  – Pressure to manufacture new products, while keeping R&D costs low and replacing lost revenues due to expiring patents

• Process Problems
  – Insufficient reporting of possible drug shortages
  – Transferring products from lab to production

• Improper information technology security and record keeping
  – Lack of security, allowing unauthorized users to gain access to IT systems, potentially causing regulatory documentation compliance issues
External Industry Pressures
Quality and Manufacturing Issues

• Insufficient knowledge of regulatory compliance requirements by Quality and Manufacturing workforce
  – Need for more experienced and better trained employees

• Tightening of FDA regulations
  – Call for stricter track and trace measures during the entire supply chain process to limit the amount of counterfeit drugs on the market

• Food and Drug Administration (FDA) Safety and Innovation Act
  – Industry user fees to fund FDA’s review of drugs and medical devices

• Patient Protection and Affordable Care Act
  – 2.3% medical device tax on revenues
    - Moving production outside of US
  – Abbreviated licensure pathway for biosimilars
    - Increase production
HOW HAVE QUALITY AND MANUFACTURING RESPONDED?
How Have Quality and Manufacturing Responded?
Industry Model Changes

• Growth in Quality and Manufacturing positions across all sub-industries of Life Sciences

• Outsourcing to Contract Manufacturing
  – Improve how organizations manage suppliers including raw materials and supply chain process

• Expanding and investing in developing Manufacturing operations outside the US

• Minimizing issues in transfer of products from R&D to Manufacturing

• Designs and formulations for reliability of Manufacturing
  – Increase process improvement
How Have Quality and Manufacturing Responded?

Industry Model Changes

• Increased focus on training employees in regulations and quality processes
• Focus on IT systems to ensure compliance and secure data systems
• Increase in post-marketing/post-production monitoring
  – Investigate adverse events and follow up with consumer complaints
    - More in depth than compliance requirements
• Stress the importance of quality to company culture
  – Incorporate metrics for quality performance
HOW DOES THIS IMPACT SIRS®?
How Does This Impact SIRS®?
Industry Trends

<table>
<thead>
<tr>
<th>Industry Trend</th>
<th>Mercer SIRS® Impact</th>
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<tbody>
<tr>
<td>Realizing the cost of any plant shutdowns, companies are focusing more on</td>
<td>Growth in all quality and manufacturing</td>
</tr>
<tr>
<td>accountability of the quality of their products</td>
<td>incumbents across all sub-industries</td>
</tr>
<tr>
<td>Facing cost constraints, companies are outsourcing to Contract Manufacturing</td>
<td>Growth in Contract Manufacturing population and</td>
</tr>
<tr>
<td>and expanding manufacturing outside the US</td>
<td>slight decrease in Manufacturing Plant</td>
</tr>
<tr>
<td>Re-examining operations, companies are creating designs and formulations for</td>
<td>Management population</td>
</tr>
<tr>
<td>reliability of manufacturing</td>
<td>Continuous Process Improvement benchmark has</td>
</tr>
<tr>
<td>As companies revamp their supply chain, they aim to minimize process</td>
<td>seen continued year over year population growth</td>
</tr>
<tr>
<td>development issues in the transfer of products from R&amp;D to Manufacturing</td>
<td>Manufacturing Process Development has seen</td>
</tr>
<tr>
<td>Companies are focusing on training employees in regulations and quality</td>
<td>higher than average base pay increases</td>
</tr>
<tr>
<td>processes to prevent future plant shutdowns</td>
<td>Growth in Internal Training population</td>
</tr>
<tr>
<td>Companies are giving more consideration to IT security and adequacy by</td>
<td>Increase of IT population in benchmarks such as Computer Systems Security</td>
</tr>
<tr>
<td>altering IT authorization procedures</td>
<td>Validation, Computer Software and Auditing- IT Compliance</td>
</tr>
<tr>
<td>Companies are taking on more product accountability, even once it reaches the</td>
<td>Creation of a new Deviation Management benchmark and growth of Product Complaint</td>
</tr>
<tr>
<td>consumer, by increasing post-marketing/post-production monitoring</td>
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</tbody>
</table>
Population growth of 11% highlights companies’ increased focus on accountability for the quality and manufacturing of products.
How Does This Impact SIRS®?
Job Family Analysis: Quality and Manufacturing

The base salary increase of 2.1% for Quality and Manufacturing is in line with movement across all job families.

This slide uses Year-Over-Year Analysis Assumptions.
How Does This Impact SIRS®?
Benchmark Analysis: S590- Manufacturing Plant Management

Currently only small drop in population of 1% from 2011 to 2012; increased use of outsourcing likely to have a larger effect on future population size.

This slide uses Year-Over-Year Analysis Assumptions
How Does This Impact SIRS®?
Benchmark Analysis: A433- Contract Manufacturing

Increase in outsourced manufacturing highlights the need for more skilled staff in the Contract Manufacturing liaison role.
Contract Manufacturing roles at SIRS® Level 5 show a 6% increase in average base salary compared to 2.1% for all positions reported at SIRS® level 5 in the manufacturing job family.
How Does This Impact SIRS®?
Benchmark Analysis: T447- Manufacturing Process Development

Average base salary growth of 4.5% across levels, compared to 2.8% for all Technical* roles in Life Sciences shows the increased importance of process development within manufacturing.

* Excluding Sales and U coded benchmarks
How Does This Impact SIRS®?
Benchmark Analysis: S551- Manufacturing Process Development

Salary increase across all levels is 4.7%; the highest base pay increase is 3.5% at level 4.
How Does This Impact SIRS®?
Benchmark Analysis: A285- Training vs. T005- Training Technical-Internal

Technical Training is a new position for the 2012 survey; overall there is a premium for this position.
BACKGROUND AND STUDY PROCESS
Background and Study Process

Executive Summary

Conducted study of 80+ Manufacturing and Quality benchmarks

Company visits with line managers and HR plus additional conference calls and independent research

Made changes and additions to 26 Quality and Manufacturing related benchmarks

Discovered changes taking place in the industry

Amgen, Inc
Boehringer Ingelheim (2 sites)
Edwards Lifesciences
Forest Laboratories (3 sites)
Sandoz a Novartis Company (2 sites)
TYPICAL ORGANIZATION STRUCTURE
The schema depicted below is designed to give an overview of the survey benchmarks. While it may depict some of the more common reporting relationships, it is not intended to represent formal reporting structures or organization charts or cover all possible roles within an organization.
DISCUSSION AND REVIEW OF BENCHMARK CHANGES
Discussion and Review of Benchmark Changes
Considerations

• Understand if a change represents a new discipline (benchmark) or a different process (interdisciplinary team staffed with traditional disciplines) or mindset

• Decide whether to create a separate benchmark, add or remove activities to existing benchmarks and/or combine or remove benchmarks

• How can we provide better matching guidance?

• At what point are new disciplines integrated into traditional disciplines?
## Discussion and Review of Benchmark Changes
### Job Sub-Families: Quality

<table>
<thead>
<tr>
<th>Sub-family Code</th>
<th>Sub-family Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>19.01</td>
<td>Quality Assurance</td>
<td>Ensures that quality control procedures adequately evaluate an organization’s products. Determines if current methods and techniques result in meeting reliability standards or require modification. (More concerned with standards, methods and procedures than with testing devices and equipment used to check products).</td>
</tr>
<tr>
<td>19.02</td>
<td>Quality Reliability</td>
<td>Devises testing plans, methods and equipment to assure reliability of product in conjunction with product design and specifications. (More concerned with tests and quality control checks during and after product preparation.)</td>
</tr>
<tr>
<td>19.03</td>
<td>Test and Inspection</td>
<td>Tests and inspects products to determine compliance with specifications. Include on- and off-line inspection.</td>
</tr>
<tr>
<td>19.04</td>
<td>Quality Control and Test Services</td>
<td>Performs tests and inspections on finished products, raw materials, packaging materials and in-process material in support of the company’s quality control program.</td>
</tr>
</tbody>
</table>
### Discussion and Review of Benchmark Changes

#### Job Sub-Families: Manufacturing

<table>
<thead>
<tr>
<th>Sub-family Code</th>
<th>Sub-family Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>21.01</td>
<td>Production Engineering</td>
<td>Determines manufacturing methods, procedures, and tooling requirements. Designs tools and plans production sequences.</td>
</tr>
<tr>
<td>21.05</td>
<td>Assembly</td>
<td>Assembles component parts, sub-assemblies or completed units. Includes electronic, electro-mechanical, mechanical, structural products, instrument, and plastic parts assembly.</td>
</tr>
<tr>
<td>21.06</td>
<td>Process</td>
<td>Changes the characteristics of material by chemical means or performs the following functions working with material: heating/cooling, bonding, laminating, plating, etching, engraving, production painting, silk screening, molding plastics, glass working, and chemical processing.</td>
</tr>
<tr>
<td>21.99</td>
<td>Manufacturing - Multiple Functions</td>
<td>Manufacturing classifications that do not meet the criteria of other subfamilies or have supervisory/management responsibilities over more than one functional area in this job family or over the entire job family.</td>
</tr>
</tbody>
</table>
Discussion and Review of Benchmark Changes
Quality Assurance Benchmarks

Quality Analysis

A073 (1 - 5)  (Administrative Level Chart)  S690 (2 - 6)  (Management Level Chart)

Add Pharmaceutical, Medical Device and Biotechnology Industry Designators

Industries: EKRN

Develops and implements program quality plans and procedures. Ensures that performance and quality products conform to established company and regulatory standards. Reviews, analyzes and reports on quality discrepancies and routine data related to production. Investigates problems and develops disposition and corrective actions for recurring discrepancies. Interfaces with stakeholders to ensure requirements are met. Recommends corrective actions, dispositions and modifications.
Discussion and Review of Benchmark Changes
Quality Assurance Benchmarks

Quality Assurance - Supplier

A429(1 - 5)  (Administrative Level Chart)  S487(2 - 6)  (Management Level Chart)

Industries: EPRM

Plans, organizes, directs and reports on all supplier quality-related activities such as raw materials, contracted designed and manufactured items, packaging materials, good manufacturing practices (GMP) service providers, and laboratories to assure procurements meet or exceed the requirements. Verifies and validates suppliers and/or subcontractors have received engineering, manufacturing, and quality requirements. Ensures that customer quality-imposed technical requirements are adhered to by suppliers and quality system is maintained. Ensures programs are in place and designed to improve supplier performance, productivity, and process validation. Prepares, maintains and reviews procurement quality assurance procedures to ensure compliance with customer and/or government requirements. Reviews and analyzes corrective action reports and purchase orders in an effort to reduce and eliminate defects. Monitors quality control activities and systems at supplier and subcontractor facilities. May monitor a certified supplier program or related programs in receiving inspection and other quality areas. May also audit third-party manufacturers to ensure due diligence and vendor selection process. May perform deviation investigations into quality issues.

Discussion and Review of Benchmark Changes
Quality Assurance Benchmarks

Engineering - Software Computerized Systems Quality

T426(1 - 6)  (Technical Level Chart)  S482(2 - 6)  (Management Level Chart)

Add all Life Sciences Industry Designators

Industries: EM

Develops, modifies, applies, and maintains standards for software computerized systems quality operating methods, processes, and procedures. Conducts evaluation of software computerized systems activities including requirements, design, development, documentation, integration, test, verification and validation. Defines appropriate measures to ensure product quality. Develops overall operating criteria to ensure implementation of the software quality program according to project, process and contract requirements and objectives. Ensures that projects and process control documentation are compliant with requirements, objectives and/or contracts. Reviews software systems design, change specifications, and plans against contractual and/or process requirements. Reviews include applicable specifications, materials, tools, techniques, and methodologies. Provides or directs verification and validation of software system requirements, traceability, and testability.

See 09.05 T439/S203 Validation Computer Software.
Discussion and Review of Benchmark Changes
Quality Assurance Benchmarks

Engineering - Quality Assurance

T430(1 - 6)  (Technical Level Chart)  S483(2 - 6)  (Management Level Chart)

Industries: EKPQRM

Develops, modifies, applies and maintains quality evaluation and control systems and protocols for processing materials into partially finished or finished materials product. Collaborates with engineering, laboratory and manufacturing production functions to ensure quality standards are in place. Devises and implements methods and procedures for inspecting, testing and evaluating the precision and accuracy of products and production equipment. Designs and analyzes inspection and testing processes, mechanisms and equipment; conducts quality assurance tests; and performs statistical analysis to assess, control and manage risks of product quality the cost of and determine the responsibility for, products or materials that do not meet required standards and specifications. Audits quality systems for development acceptance criteria (parameters based on product result). For deficiency identification and correction. May undertake root cause analysis of incidents requiring corrective action once product has been released. Ensures that corrective measures and deviation meet acceptable reliability standards and that documentation is compliant with requirements. May specialize in the areas of design, incoming material, production control, product evaluation and reliability, inventory control and/or research and development as they apply to product or process quality. May be certified in lean and six-sigma quality engineering methodologies.
Discussion and Review of Benchmark Changes
Quality Assurance Benchmarks

Quality Assurance - Compliance

**T431** (1 - 5)  *(Technical Level Chart)*  **S486** (2 - 7)  *(Management Level Chart)*

**Industries:** EKLPQRMN

Provides oversight for the development and maintenance of quality programs, *systems*, processes and procedures that ensure compliance with policies and that the performance and quality of services conform to established standards and agency guidelines. Provides expertise and guidance in interpreting policies, regulatory and/or governmental regulations, and agency guidelines to assure compliance. Works directly with operating entities to provide process analyses oversight on a continuing basis to enforce requirements and meet guidelines. Leads audit and inspection preparation, resolution of audit and inspection findings and liaises with auditing groups and inspectors through all stages of the audits. Co-ordinates legal requests in support of government investigations or litigations. Ensures the quality assurance programs and policies are maintained and modified regularly. Facilitates uniform standards worldwide and enables best practice sharing, thereby fostering the achievement of company's mission globally.

*See 19.04 T433/S489 - Quality Control for positions that conduct tests and inspections.*
Discussion and Review of Benchmark Changes
Quality Assurance Benchmarks

Quality Assurance Documentation

T436(1 - 4)  (Technical Level Chart)  S495(2 - 4)  (Management Level Chart)

Industries: PQRMNR

Prepares, issues and reviews required documentation such as good practice quality guidelines and regulations (GxP) procedure manuals, quality control manuals, engineering documents, manufacturing production instructions, and change authorizations in accordance with company policy and government regulations. Implements related documentation systems. Proposes and implements change control processes. Coordinates the review and revision of procedures, specifications, and forms. Provides input on quality control procedures and R&D documentation.
Discussion and Review of Benchmark Changes
Quality Assurance Benchmarks

Good Laboratory Practices (GLP)

T437(1 - 5)  *(Technical Level Chart)*  S496(2 - 4)  *(Management Level Chart)*

**Industries:** PQN

Performs detailed audits of practices at company laboratory and R&D sites to ensure that policies and procedures comply with guidelines set forth by regulatory agencies. Works with product safety evaluation and reports on weaknesses, ineffective procedures, policy exceptions and reporting discrepancies and recommends appropriate corrective actions. Consults with laboratory management to establish practices and procedures that comply with regulatory agencies. **May review and verify technical data such as chromatograms.** May include training.
Discussion and Review of Benchmark Changes
Quality Assurance Benchmarks

Quality Assurance, In-Process and Release Control

T438(1 - 5) (Technical Level Chart)   S497(1 - 6) (Management Level Chart)

Industries: PQRMN

Assesses, evaluates and reviews results of analytical manufacturing tests and/or reviews manufacturing and release documents to determine if product/material specifications are met. Ensures that established sampling and statistical process control procedures are followed. Identifies and reviews deviations from established standards in the manufacturing and/or packaging of products. Ensures that customer and regulatory requirements are implemented and reviews change accounting activity to ensure compliance. with configuration management policies. Determines the disposition of materials, semi-finished and finished products. Acts as final control checkpoint for final and/or in-process–release authorization.
Discussion and Review of Benchmark Changes
Quality Assurance Benchmarks

Good Clinical Practices (GCP)

**T448**(1 - 4)  *(Technical Level Chart)*  **S915**(3 - 6)  *(Management Level Chart)*

**Industries:** PQRM

Completes audits to assess accuracy and quality of scientific data submitted to the regulatory agencies in support of new drug application, biological licensing agreement, animal drug application or medical devices application. Conducts investigations to ensure conformance to regulations and company standard operating procedures. Documents audit observations and makes recommendations for corrective action. May create and maintain clinical quality assurance databases, reports, and files. May act as an advisor on clinical quality assurance protocol, amendments and/or biological licensing agreements. May also audit operating systems, processes and procedures. May support risk management operations, including ongoing review of literature and compilation and interpretation of safety data to support product strategies. May plan and prepare report drafts for products and safety issues for regulatory submission. May use six-sigma methodology. **May provide training on GCP and current regulations for those undertaking clinical studies.**
Discussion and Review of Benchmark Changes
Quality Assurance Benchmarks

Good Manufacturing Practices (GMP)

T470 (1 - 4)  (Technical Level Chart)  S913 (2 - 4)  (Management Level Chart)

Industries: EPQRMN

Develops and performs detailed audits of practices at company manufacturing plants and sites to ensure that policies and procedures comply with guidelines set forth by all applicable regulations both domestic, international, and applicable International Standardization for Organization (ISO) standards. Reports on weaknesses, ineffective procedures, policy exceptions and discrepancies and recommends appropriate corrective actions. Consults with manufacturing management to establish practices and procedures that comply with all applicable regulations. May act as an advisor on clinical quality assurance protocol amendments and/or biological licensing agreements. May include training.
Discussion and Review of Benchmark Changes
Quality Reliability

Engineering - Reliability

T432(1 - 5)  (Technical Level Chart)  S493(2 - 6)  (Management Level Chart)

Industries: EM

Develops, coordinates and conducts technical reliability studies and evaluations of engineering design concepts and design of experiments (DOE) constructs. Recommends design or test methods and statistical process control procedures for achieving required levels of product reliability. **Completes risk analysis studies of new design and processes.** Compiles and analyzes performance reports and process control statistics; investigates and analyzes relevant variables potentially affecting product and processes. Ensures that corrective measures meet acceptable reliability standards. Analyzes preliminary plans and develops reliability engineering programs to achieve company, customer and governmental agency reliability objectives. May develop mathematical models to identify units, batches or processes posing excessive failure risks. As necessary, proposes changes in design or formulation to improve system and/or process reliability. May determine units and/or batches requiring environmental testing, and specifies minimum number of samples to obtain statistically valid data.
Discussion and Review of Benchmark Changes
Test and Inspection

Inspector - Receiving

M623(2 - 3)  (Support Level Chart)

Add Pharmaceutical and Biotechnology Industry designators.

Industries: EM

Inspects purchased parts and materials for conformity to standards, specifications, and processing requirements. Inspects for proper identity and dimensions using such measuring devices as micrometers, gauges, and calipers. Visually inspects for obvious defects or damage such as corrosion, cracks, dents, scratches, and pits. Verifies specifications using purchase orders, blueprints, drawing or inspection instructions, and checklists. Makes pass/fail decisions on inspected goods. Maintains records of results. Inspections may involve compound angles or three-dimensional projections using inspection equipment such as microscopes, micrometers, telescope gauges, and optical comparators.
Discussion and Review of Benchmark Changes
Test and Inspection

Inspector

M629(1 - 4)  (Support Level Chart)

Industries: EKPQRM

Uses predetermined methods, operations, setups and prescribed specifications to inspect visually in-process and completed products such as electronic units and subsystems, precision electromechanical assemblies or mechanical units, subassemblies, structural flaws, internal defects, and missing welds. Uses various measuring devices and operates functional testing equipment. Accepts, rejects, or reworks defective or malfunctioning units or systems. Works from blueprints, diagrams, dial indicators, preset micrometers, scales, fixtures, customer specifications, drawing or inspection instructions and checklists. May monitor and verify quality in accordance with statistical process or other control procedures. Performs line clearances after each lot to ensure all materials from the previous lot have been removed.
Discussion and Review of Benchmark Changes
Quality Control and Test Services

Technician – Quality

K612(1 - 4)  (Support Level Chart)

Industries: EKLPQRM

Performs analyses and inspection tests of raw materials, packaging materials, and/or finished products from manufacturing, to ensure quality standards and compliance to customer and regulatory requirements, and tolerance specifications for the chemical or physical property. Performs a variety of qualitative tests or qualitative assays on samples, and to aid in maintenance and certification of test instruments and apparatus to ensure compliance. Performs sample receipt, labeling, placement on condition, removal at defined intervals, and sample distribution in accordance with approved procedures and protocols. Performs required inspections, checks, analysis and documentation of studies. Prepares and monitors quality statistics and reports. Reviews production records for conformance to procedures. Conducts non-conformance tests of manufactured, packaged or tested product. Performs qualitative tests or quantitative assays on samples using techniques that vary from use of standard analytical equipment to highly modern and automated instrumentation.

See 18.03 K588 Technician-Laboratory for incumbents working in R&D laboratories.
Discussion and Review of Benchmark Changes
Quality Control and Test Services

Validation Analysis – Quality Process

T434(1 - 4)  (Technical Level Chart)  S484(1 - 6)  (Management Level Chart)

Suggestion to move to 19.02- Quality Reliability

Industries: PQRMN

Develops and evaluates quality assessment process and system standards to ensure reliability and compliance with company standards and governmental regulatory requirements. Investigates/troubleshoots validation problems for systems equipment and/or performance processes; conducts statistical analyses of testing results and process anomalies; writes, reviews, approves and/or executes documentation for new and current validation procedures and technical reports related to systems equipment, products and/or processes. Ensures that corrective measures meet acceptable reliability standards. Verifies calibration, maintenance and repair of the instruments. May assist with establishing corporate validation policies.

See 19.03 K606-Technician Calibration.
Discussion and Review of Benchmark Changes
Quality Control and Test Services

Quality Control, Analysis and Test Services

T435(1 - 5)  (Technical Level Chart)  S494(1 - 6)  (Management Level Chart)

Industries: EKPQRMN

Analyzes chemical, biological or microbiological products, raw materials, in-process materials, release test samples or stability samples in support of the company's quality program compliance with company standards and governmental regulatory requirements. Interprets and evaluates the analyses in terms of accuracy and precision compared against established specifications and recommends and implements corrective action where necessary. Develops, validates, and implements controlled environment methods. Applies existing techniques and procedures with recommendations and implementation of modification for improved efficiency, or devises and develops new analytical methods and techniques. Performs qualitative tests or quantitative assays on samples using techniques that vary from use of standard analytical equipment to highly modern and automated instrumentation. May also be involved in establishing requirements for the transfer of methodology from R&D. May be responsible for analytical and protocol report writing and standard operating procedures and may be responsible for maintaining lab equipment and reagent preparation and quality.
Discussion and Review of Benchmark Changes
Information Technology - Quality

Validation Computer Software

T439 (1 - 4)  (Technical Level Chart)  S203 (3 - 6)  (Management Level Chart)

Industries: EPQRM

Conducts a compliant validation process for quality information technology systems which requires formal validation documentation (including standard operating procedures) under appropriate federal regulations. Coordinates activities with clients, programmers/developers and operating personnel, domestic and, as appropriate, global. Identifies current and anticipated requirements for compliant computerized operations and suggests methods for the identification, implementation and maintenance of the procedures, actions and documentation necessary to assure compliance according to the appropriate federal and international regulations which govern the user's applications. **Performs system administration and configuration of quality information technology systems.** Reports on the status of validation activities to fulfill regulatory requirements. Keeps abreast of changing federal and international regulatory requirements, government audit policies, and the availability of current techniques.
Discussion and Review of Benchmark Changes
Production Engineering

Engineering - Industrial

T442(1 - 5)  (Technical Level Chart)  S526(2 - 6)  (Management Level Chart)

Industries: AEKPM

Analyzes and designs sequence of operations and work flow to improve efficiencies in plant and production facilities and equipment layouts; and establishes methods for maximum utilization of production facilities and personnel. May establish or assist in establishing accident prevention measures and may manage training programs for personnel concerning all phases of production operations. Conducts studies pertaining to cost control, cost reduction, inventory control, and production record systems. On the basis of these studies, develops and implements plans and programs for facility modifications and revisions to operating methods. **Conducts continuous process improvement methods.** May assist facilities engineers in the planning and design of facilities.

See 13.03 T421/S302 - Engineering-Equipment Design.
Discussion and Review of Benchmark Changes
Production Engineering

Engineering - Chemical Pharmaceutical/Biological Process

T444(1 - 5) (Technical Level Chart) S530(2 - 6) (Management Level Chart)

Industries: EKLPQRN

Implements and maintains chemical pharmaceutical/biological processes; calculates and organizes all data for complex process flow sheets including instrumentation and control considerations; models processes and units operations. Ensures proper sequence of operation and prepares specifications and operating instructions for processing equipment. Conducts tests and measurements throughout stages of production to determine control over such variables as temperature, density, pressure and viscosity. Services, troubleshoots, and solves engineering problems with processes or equipment already in operation. Ensures processes and procedures are in compliance with regulations. May be responsible for corrective and preventative actions and investigation management.

Discussion and Review of Benchmark Changes
Production Engineering

Manufacturing Process Development

**T447**(1 - 5)  *(Technical Level Chart)*  **S551**(2 - 6)  *(Management Level Chart)*

**Industries:** PQRMN

Designs and develops manufacturing processes for drug products, taking into consideration problems inherent in the transfer of technology from research to manufacturing. Such design and development may include new or revised dosage processes. Develops procedures for the economical mass production in cooperation with pilot-plant and production departments. Conducts tests and measurements throughout stages of production to determine control over applicable variables; and services, troubleshoots and solves production process problems with processes or equipment already in operation. Requires understanding of compliance, pharmaceutical, pharmacological, biological, biochemical, medical, patent and commercial factors. **Makes recommendations concerning acquisition and use of new technological equipment and materials.**
Discussion and Review of Benchmark Changes
Assembly

Packager/Assembler

**M790 (1 - 4)**  *(Support Level Chart)*

**Industries:** EKPQRMN

Sets up, operates, maintains, and troubleshoots packaging equipment. Monitors, evaluates and adjusts processes or packaging equipment to maximize quality and efficiency. Operates equipment that packages materials or products by inserting them into containers or filling containers from spouts or chutes. Completes the batch records and associated documentation. Works in an integrated computerized manufacturing environment. Tasks are performed in accordance with applicable safety guidelines, as well as appropriate processing standards. **May monitor and verify quality in accordance with statistical process or other control procedures.** Must pass all job-specific or specialized certification programs required for core tasks or specialized assignments. May provide training to less experienced team members. Participates in program or functional team projects developing process improvement methods, solutions, and procedures to enhance program quality, cost, and scheduling.

*See 21.05 M745 - Assembler.*
Discussion and Review of Benchmark Changes
Process

Pharmaceutical Operator

M820(1 - 4) (Support Level Chart)

Industries: PQR

Performs a variety of tasks related to the processing of ingredients and/or pharmaceutical products. Operates general manufacturing equipment, such as autoclaves, ovens, stills, filtration apparatus. Handles raw materials and intermediate or finished products. Mixes compound ingredients for liquid products, suspensions, ointments, mixes, or blends for tablet granulations and capsule powders. Performs general maintenance as required on pumps, homogenizers, filter presses, tablet compression machines, etc. Performs standard operating procedures to meet current good manufacturing practices (GMP). Maintains records as required. May monitor and verify quality in accordance with statistical process or other control procedures. Must pass all job-specific or specialized certification programs required for core tasks or specialized assignments. May provide training to less experienced team members. Participates in program or functional team projects developing process improvement methods, solutions, and procedures to enhance program quality, cost, and scheduling.
Discussion and Review of Benchmark Changes
Manufacturing – Multiple Functions

Third Party Contract Manufacturing

A433(2-4) (Administrative Level Chart) S554(2-7) (Management Level Chart)

Industries: KPQRN

Responsible for managing quality, compliance and regulatory aspects of manufacturing contracts supplied by contractors and suppliers including relationship management, technical issues, vendor selection and evaluation, schedule conflicts, and quality issues. Provides contractors with the proper information to ensure that contractors meet quality standards. Acts as liaison between company and contractors to ensure all products are manufactured following good manufacturing practices (GMPs) and quality products are released and available to meet customer needs. Identifies potential new contractors and evaluates financial stability of new suppliers. Coordinates the development of documentation for contractor manual. Ensures that the product is available to meet customer needs. May respond to requests for cost and feasibility reports and obtains vendor quotations. May be responsible for transferring technology to the contractor including analytical testing methods, manufacturing processes and procedures.
Discussion and Review of Benchmark Changes
Proposed New Benchmarks – Quality Assurance

QUALITY ASSURANCE-DEVIATION MANAGEMENT

Txxx (1-4) / Sxxx (2-5)

Family 19.01

Industries: KPQRM

Processes, investigates deviations, serving as primary contact. Addresses and expedites product deviation under the company's quality management system procedures, and ensures compliance with regulatory agencies. Monitors, investigates deviations and determines corrective and preventive actions to appropriate company authorities to modify existing manufacturing or packaging process based upon trend, deviation and related analyses. Maintains unified product defect investigation operating procedures. Provides technical expertise to optimize deviations management, corrective and preventive actions effectiveness and prevents reoccurring events. Maintains and monitors systems to ensure that all deviations received are appropriately investigated and concluded per the company's complaint handling procedure.
Discussion and Review of Benchmark Changes
Proposed New Benchmarks – Quality Assurance

QUALITY ASSURANCE- PHARMACOVIGILANCE

Txxx (1-5) / Sxxx (2-6)

Family 19.01

Plans and conducts pharmacovigilance system audits in support of post marketed and clinical development products. Ensures that policies and procedures comply with guidelines set forth by regulatory agencies. Audits and evaluates proposed corrections, corrective actions, and/or preventative actions for compliance with applicable regulations, guidelines, and company policies. Facilitates risk mitigation and escalates inadequate audit responses. Provides interpretations, consultations, trainings, and other supportive services necessary to maintain and improve the quality systems in Pharmacovigilance in support of both developmental and post marketing drug safety activities. Identifies potential systemic compliance risks, through audit activities and data analysis. Contributes to the development of process improvement initiatives that enhance regulatory compliance and Pharmacovigilance / Quality Assurance efficiencies.
QUALITY ASSURANCE-SUBSTANCE CONTROL COMPLIANCE

Axxx (1-5) / Sxxx (2-6)

Family 19.01

Provide oversight for dispensing, processing, sampling, testing and warehousing operation processes to ensure compliance to Drug Enforcement Agency (DEA), Federal Drug Administration (FDA) and State regulatory requirements for the handling and processing of controlled substance materials and products. Conducts day-to-day DEA compliance activities. Reviews controlled substances-related operations including, but are not limited to, receiving, quarantining, distribution, and documenting the destruction of controlled substances. Reviews reports and investigation of controlled substances-related non-conformance events. Coordinates, establishes and/or maintains DEA compliance readiness in existing and new business activities. Writes, reviews and revises controlled substance related standard operating procedures as necessary to meet cGMP and DEA requirements.
APPENDIX - GEOGRAPHIC ANALYSIS IN QUALITY AND MANUFACTURING
Data and Compensation Analysis
SIRS Geographic Total Cash Compensation: By Sub-Area Manufacturing

Salary Source: Mercer SIRS® 2012 Benchmark Surveys (Effective April 1, 2012)
Data and Compensation Analysis
SIRS Geographic Total Cash Compensation: By Sub-Area Quality

Salary Source: Mercer SIRS® 2012 Benchmark Surveys (Effective April 1, 2012)