

Promoting Quality OINDP Components- A Supplier Perspective

Tom Gaspar
Vice President Quality Assurance,
Manufacturing and Development Support
West Pharmaceutical Services

IPAC-RS Conference November 2006

1



Overview

- n The "Desired State" for Suppliers
- n Role of IPAC-RS Guideline
- n Product Realization
- n Key Components of a Quality System
- n How do I Get from Here to There?

IPAC-RS Conference November2006

2



The "Desired State" for Suppliers

Quality is Moving to the Next Level

Now Specification (AQL) → Now/Future Specification (6 σ ; 3.4dpm; 0 defects; Cpk)



The "Desired State" for Suppliers

Product Assessment

Final QC Sampling (statistical sampling ANSI/ASQ Z1.4) → Quality by Design (In-process controls, PAT, Continuous Monitoring, Verification)



The “Desired State” for Suppliers

- n To move from Today to Tomorrow suppliers to the OINDP industry must:
 - ∅ Understand the Customer Requirements
 - ∅ Design the product and process to produce and deliver the product as required
 - ∅ Establish “controls” to ensure continuous production to requirements
 - ∅ Establish feedback loops (internal/external) to continuously improve the process/product



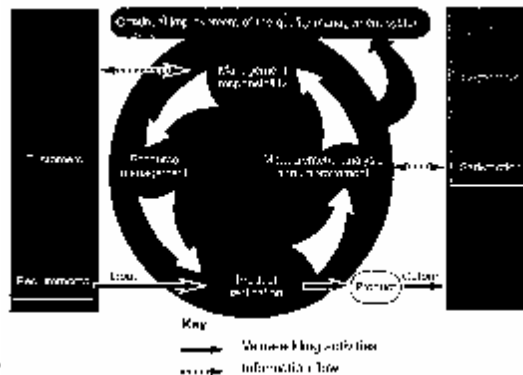
Quality Management System

- n A Quality Management System Provides the Infrastructure to Accomplish Product Realization, Product Conformance, and Product Improvement

Role of IPAC-RS GMP Guideline

- n IPAC-RS GMP Guideline for Suppliers of Components for OINDP is a blueprint to follow in building a Quality Management System

From ISO 9000:2001
Section 0.2 Figure 1



IPAC-RS Conference Novemb

7

Role of IPAC-RS GMP Guideline

- n IPAC-RS Guideline is complementary to ISO 9001:2000 and PS 9000:2001
 - o Also is in alignment with 21 CFR 210-211 and 820
- n The IPAC-RS Guideline fits in with the current thinking on Quality by Design and Quality Management Systems and is in line with the direction of the industry

IPAC-RS Conference November2006

8



Product Realization: Quality by Design

n Design Requirements

- ø Inputs
- ø Outputs
- ø Validation
- ø Verification
- ø Changes

n Process Control

n Purchasing Control

IPAC-RS Conference November2006

9



Tools for Continuous Improvement

n Measurement, Analysis and Improvements

- ø Statistical Techniques
- ø Receiving Inspection
- ø In-process Inspection/Monitoring
- ø Final Inspection
- ø Audits
- ø Corrective/Preventive Actions
- ø Customer Feedback
- ø Workforce Feedback

IPAC-RS Conference November2006

10



Product Realization: QbD

n Management Responsibilities

- ∅ Quality Organization
- ∅ Quality Policy
- ∅ Responsibilities
- ∅ Document and Data Control



Product Realization: QbD

n Resource Management

- ∅ Available Resources at all Levels
- ∅ Training
- ∅ Resource Feedback



Product Realization: QbD

n In Building Quality for the Customer
the Supplier Must

LISTEN



Who is Involved in the Conversation?

Customer

Customer Design
Engineer

Customer Operations

Customer QA

Supplier

Supplier Design
Engineer

Supplier Operations

Supplier QA

Supplier Purchasing



Product Realization: QbD

n Inputs

- ∅ Define Requirements at all Levels (Present/Future)
 - n Equipment
 - n Controls
 - n Documentation
 - n Resources
 - n Etc.



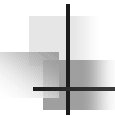
Product Realization: QbD

- n Requirements will be Used in Designing the Product, the Manufacturing Process and Controls
- n Outputs
 - ∅ Final Product Requirements agreed to
 - ∅ Product can be Measured against Requirements
 - ∅ Areas of Future Improvement Defined




Product Realization: QbD

- n Validate to Requirements
- n Process Controls



Key Components of a Quality System

- n Change Control
 - ø Process Improvements/Equipment Improvements Need to be Captured Under Change Control
 - ø Corrective and Preventive Actions Need to be Captured Under Change Control
 - ø Ensures Process Remains in a Validated State
 - ø Ensure Requirements Continue to be Met or Exceeded



Key Components of a Quality System

- n Process Control

- ø Operation Set-up and Verification

- n Manual and Documented


- n Computerized – Validated Manufacturing Execution System

- ø In-Process Inspection/Monitoring

- n Statistical Process Control

- n Process Audits

- n In-line PAT



Key Components of a Quality System


- n Process Control (Cont'd)

- ø Final QC

- ø Batch Record Review

- n Manual Documentation Review

- n Electronic Batch Record Review




Key Components of a Quality System

- n Continuous Improvement
 - ø LISTEN to the PROCESS (Develop systems to capture information/data for analysis)
 - n Scrap Rate
 - n Downtime
 - n Final Product Rejection
 - n Rework
 - n Reprocess
 - n Throughput

IPAC-RS Conference November 2006

21




Key Components of a Quality System

- n Continuous Improvement
 - ø LISTEN to the CUSTOMER (Develop system to capture information/data for analysis)
 - n Audits
 - n Complaints
 - n Inquiries
 - n Rejections
 - n Customer surveys
 - n Market trends

IPAC-RS Conference November 2006

22



Key Components of a Quality System

- n Continuous Improvement
 - o Analyze the Information/Data
 - o Prioritize
 - o Define Corrective/Preventive Actions
 - o Institute Change Control
 - o Validate/Qualify
 - o Measure Effectiveness
 - o Update Quality System
 - o Redefine Requirements

IPAC-RS Conference November 2006

23



Getting There: the IPAC-RS GMP Guideline

- n The GMP Guideline for Suppliers of Components for OINDP provides the blueprint
 - o Follows from and in line with ISO 9001:2000, 21 CFR 210-211 and 820, and PS 9000
- n Your organization must decide the implementation plan
- n By following the blueprint you will build a Quality Management System that will house a Quality by Design program

IPAC-RS Conference November 2006

24