Model Compliance Program, For PET Manufacturing Management Perspective

Anwer Rizvi
Sr. VP Government Affairs, Policy and Industry Relations

Two Topic Imaging Workshop:
Industry Perspective on PET Drug Manufacturing Panel

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Objective

- Why the GMP is critical to the success of our Industry
- Role of CMC in your organization, Specially to those who come purely from Nuclear Pharmacy.
- Role of QA, and why you may need to get the best talent from Pharma- Understand what FDA wants you to do!
- Why is it important to organize Steering Committee on compliance-
- Why should you focus on critical items first(project based approach)
- Why should you establish a guidance document for each product
- Make quality, a Strategic imperative in your organization
- Assure that you are consistent with all processes within your organization, think total product lifecycle
- From Organization perspective, inoculate quality as a shared value
- Knowledge, establish a system to manage quality based knowledge –Shortage of subject matter experts
Guidance

PET Drugs — Current Good Manufacturing Practice (CGMP) ! IS A GOOD THING FOR INDUSTRY

BUT....... To be answered later in the presentation
Outline

- Why is it important to transform Our business to pharma mode
- Where is Radiopharma business going?
- Where do we start compliance?
- How do we organize compliance?
- Long-Term View, what is a must for continued success
Why is it important to Transform Our business to Pharma?

Better Technologies are now available
Outline

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Where is Nuclear Medicine going?

- PET RADIOPHARMACEUTICAL POTENTIAL MARKET

Today (2009) = 2-2.3M Procedures

Vision for tomorrow (2020) = 12-15M Procedures

* Others = FLT, FMISO, FCHOLINE and other non proprietary
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Quality is built in at development stage

- R&D
- CMC (GMP)
- QC (GLP)
- Equipment development (ISO13485)

Integrated solution

Clinical trials
- NDA

Operations
- Customer

SUPPORT
- hands on procedure development
- technical expertise
- clinical expertise
- customer focus and contact
- sale of MA
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How do we organize: Define responsibilities, under QA control

Quality Assurance and Quality Control

- Steering Committee
- Facility Construction Experts
- Technical /Equipment Experts
- Finance (CAPX)
- Operations management
How do we Organize: GMP Quality Management System – FDA expectations

- Roles and responsibilities
- CAPA
- Product complaints
- Investigations
- Reporting
- Training

QA

Areas of control

Environment, Facility, Equip
- Facility master plans
- Equipment and process validation
- Environmental controls
- Equipment service
- Facility security
- Data management

Manufacturing
- Isotope production
- Synthesis
- Purification
- Formulation
- Final product labeling
- Aseptic processing
- Stability

Laboratory
- Product release tests
- In process testing
- Operator qualification
- Equipment qualification
- OOS handling

Materials
- Active ingredients
- Components
- Reagents and solvents
- Containers/closures
- Labeling
- Storage conditions
- Stability
How do we organize: PROJECT USP 212 – Transformation from 823 to 212

Project Goals
To ensure that all facilities are FDA compliant, enhancing regulatory compliance, safety and quality of product.

Project Scope
212 implementation at all US production facilities. Outcome will be successful internal and external 212 based audits throughout the organization.

Implementing -212 ……

Focus Area 1: SOP Revision, Development, Training and Implementation
Focus Area 2: Equipment Requirements
Focus Area 3: Facility Requirements
Focus Area 4: Facility Construction Requirements
Focus Area 5: Auditing and Oversight
Focus Area 6: Recordkeeping
Focus Area 7: Staffing and Management: Corporate and Field

Mobilization Requires
- Project Organization & Planning
- Team Selection and Resource Mobilization
- Cap Ex Approvals and Analysis
How do we Organize: Develop a guidance documentation

- General QMS documents
- Qualification, V&V
- Operational documents
- Specifications
- Work instructions
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HOW DO YOU PREPARE FOR BROADER LONG-TERM

**Strategic Imperatives**
- Quality needs to be integrated as part of the overall vision and strategy
- Nuclear Pharmacy to Pharma model
- Not just adherence to standards but exceeding them
- Bringing down the cost of quality by making quality as a “way of life and work”
- Increasing accountability related to quality

**Processes**
- **Consistent** and Advanced processes need to be implemented across the company
- These processes must cover the *total product lifecycle*

**Organizational**
- Embed **Quality mindset** in our culture
- Enhance Training and Awareness
- Continuous improvement
- Fully integrate Quality with Lean program
- **Inculcate quality as a shared value**
- **Implement reward/punishment system tied to compliance**

**Knowledge**
- Establish a system for Quality knowledge management
- **Long-term increase in organizational knowledge**
- Shared capability building across the company – instead of each unit separately.
Guidance

PET Drugs — Current Good Manufacturing Practice (CGMP) ! IS A GOOD THING FOR INDUSTRY

BUT, WE NEED HELP FROM FDA, FDA/INDUSTRY PARTNERSHIP IS A MUST FOR THIS TRANSFORMATION

Collectively, Industry will invest over $50M on Compliance over next few years, we need to do it right the first time!