Model Compliance Program, For PET Manufacturing Management Perspective

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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

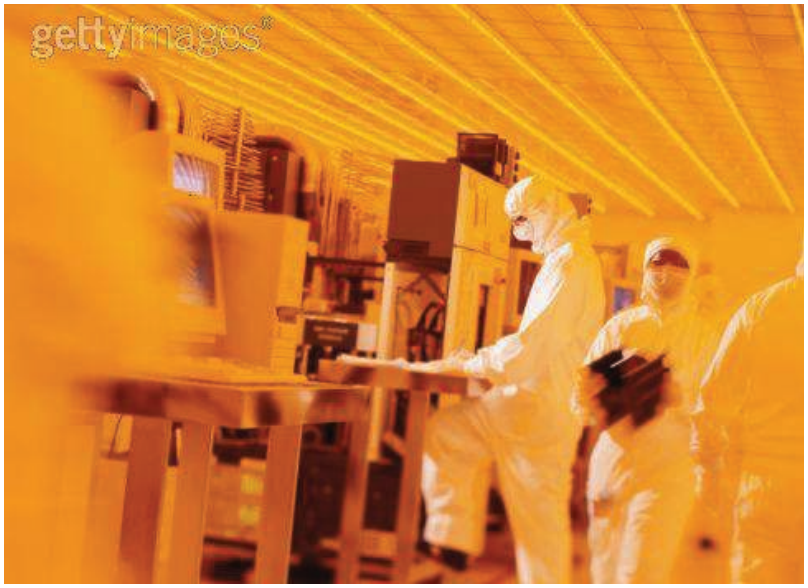
PET Drugs — Current Good Manufacturing Practice (CGMP) ! IS A GOOD THING FOR INDUSTRY

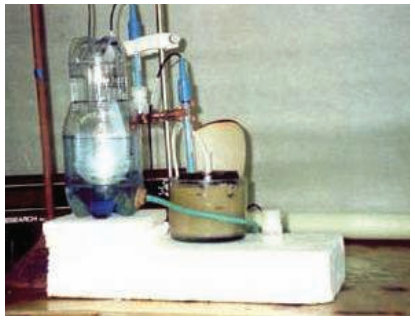
BUT……. To be answered later in the presentation

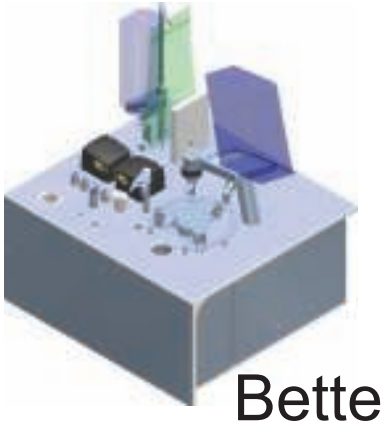
Outline

- 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 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

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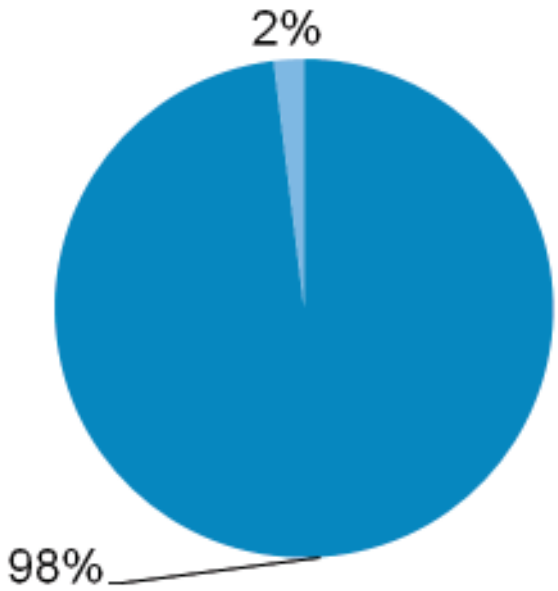
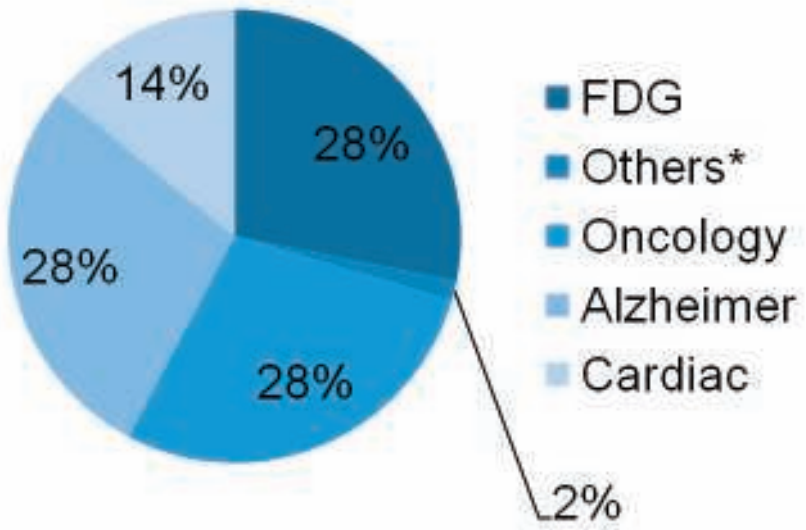
Where is Nuclear Medicine going?

- 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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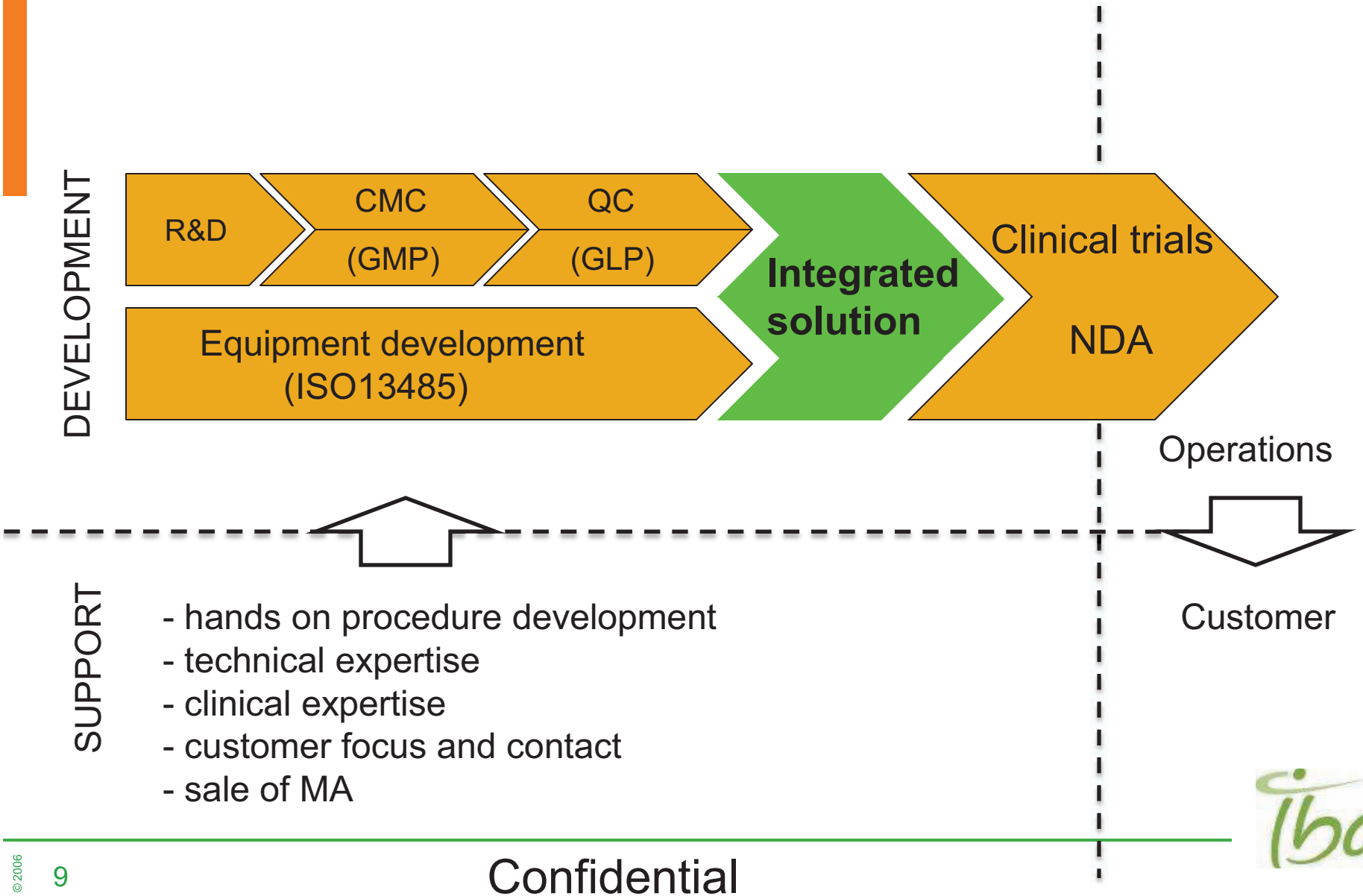
Quality is built in at development stage



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How do we organize: Define responsibilities, under QA control

Steering Committee

Quality Assurance and Quality Control

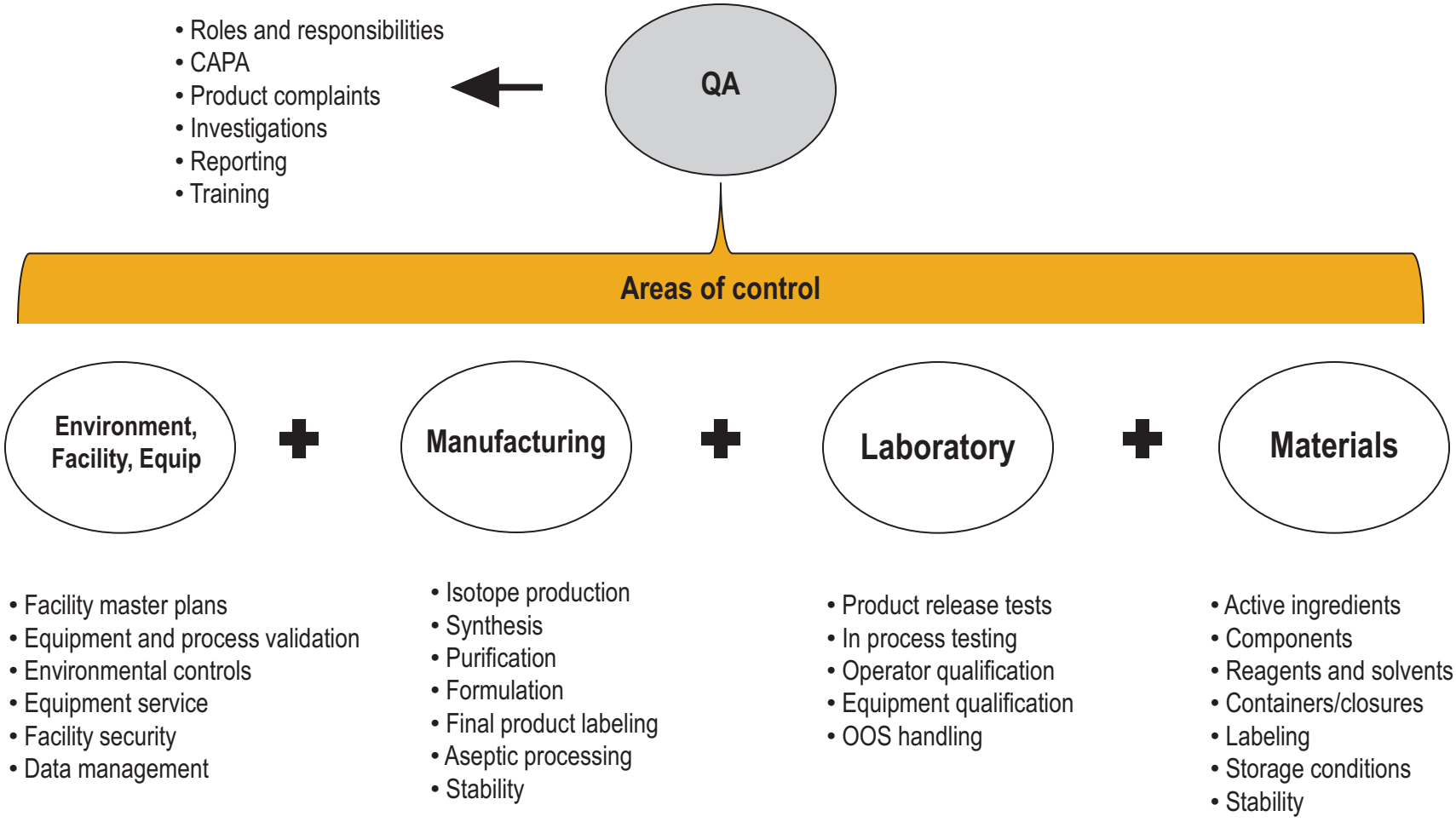
Facility Construction Experts

Technical /Equipment Experts

Finance (CAPX)

Operations management

How do we Organize: GMP Quality Management System – FDA expectations



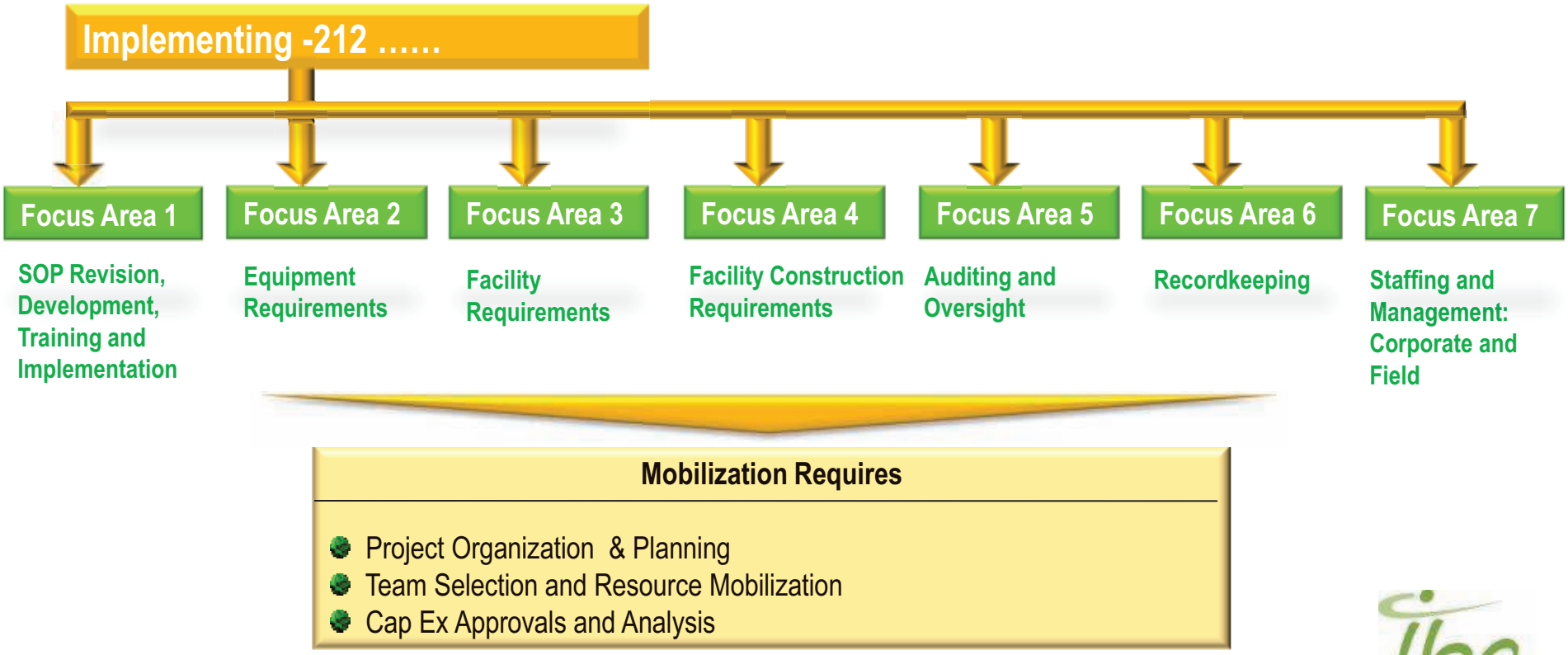
How do we organize: PROJECT USP 212 – Transformation from 823 to 212

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.



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	Processes	Organizational	Knowledge
➢ Quality needs to be integrated as part of the **overall vision and strategy**	➢ **Consistent** and Advanced processes need to be implemented across the company	➢ Embed **Quality mindset** in our culture	➢ Establish a system for Quality knowledge management
➢ Nuclear Pharmacy to **Pharma model**	➢ These processes must cover the **total product lifecycle**	➢ Enhance Training and Awareness	➢ **Long-term increase in organizational knowledge**
➢ Not just adherence to standards but **exceeding** them		➢ Continuous improvement	➢ Shared **capability building across the company –** instead of each unit separately.
➢ Bringing down the cost of quality by making **quality as a "way of life and work"**		➢ Fully integrate Quality with Lean program	
➢ **Increasing accountability** related to quality		➢ **Inculcate quality as a shared value**	
		➢ **Implement reward/punishment system tied to compliance**	

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 TRANFORMATION

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