“How Pharma Should Monitor itself for GMP Compliance”
&
“How FDA Inspections Could Incorporate Pharmaceutical Inspection Cooperation Scheme (PIC/S)”

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Food and Drug Administration
Topics:

Part I: How Pharma Should Monitor itself for GMP Compliance

Part II: How FDA Inspections Could Incorporate Pharmaceutical Inspection Cooperation Scheme (PIC/S)
Part I:

“How Pharma Should Monitor itself for GMP Compliance”
“How Pharma Should Monitor itself for GMP Compliance,”

- Internal Audits: FDA is not privy to internal audits on inspections. However corrective and preventive actions resulting from audits may be inspected.
- Potential use of qualified external consultants based on GAP analysis
- Mock Inspections for GMP purposes
- Mock Inspections for Pre-Approval purposes
“How Pharma Should Monitor itself for GMP Compliance,”

• Independent Mock Inspections for Pre-approval purposes

• Our expectation is that firms are utilizing continuous improvement

• Self evaluate whether your current system adequately manages continuous improvement

• Annual Reviews may not be sufficient (21 CFR 211.180e)
“How Pharma Should Monitor itself for GMP Compliance,”

• Significant Issues with raw materials & components
• Evaluating supply chain
• Do you know where your excipients are coming from? Execute a Mock Interstate documentation collection in preparing for inspections
• Looking at metrics
• Process improvement
“How Pharma Should Monitor itself for GMP Compliance,”

- Corrective and Preventive Actions (CAPA)
  - System to manage
  - Quality Unit Oversight
  - Timeliness
  - Prevention of recidivist issues
  - Repeat violations result in further regulatory action
“How Pharma Should Monitor itself for GMP Compliance,“

Be Aware of:

- Current Global Regulatory Activities
- New guidance
- Global compliance issues
- FOI requests
- Public information
- Industry wide Warning Letters
- Recent violators in the news
Part II:

“How FDA Inspections Could Incorporate Pharmaceutical Inspection Cooperation Scheme (PIC/S)”
Pharmaceutical Inspection Cooperation Scheme (PIC/S)

PIC/S

• Founded on November 2\textsuperscript{nd} 1995

• The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S) are two international instruments between countries and pharmaceutical inspection authorities, which provide together an active and constructive co-operation in the field of GMP.
PIC/S' mission

- To lead the international development, implementation and maintenance of harmonized Good Manufacturing Practice (GMP) standards and quality systems of inspectorates in the field of medicinal products.

- To be achieved by developing and promoting harmonised GMP standards and guidance documents; training competent authorities, in particular inspectors; assessing (and reassessing) inspectorates; and facilitating the co-operation and networking for competent authorities and international organizations.
Pharmaceutical Inspection Cooperation Scheme (PIC/S)

Membership

• There are currently 39 Participating Authorities in PIC/S (Convention and Scheme taken together).
• FDA is the 38th member.
• Meet twice annually to collaborate with other international Inspectorates to share Best Practices.
Admission Criteria

• This Scheme is open for participation by participating authorities having the arrangements necessary to apply an inspection system comparable to that referred to in this Scheme and whose requirements and procedures could ensure the proper implementation of the Scheme and contribute to its effective operation.
Admission Criteria (cont.)

The Participating Authorities should in particular ensure that:

(a) the inspectors in their service have appropriate qualifications and experience for the tasks to be undertaken by them,

(b) the inspectors and/or the control laboratories have the power to call for the submission of quality control records and, where appropriate, samples relating to any batch of any medicinal products,
Admission Criteria (cont.)

(c) the inspectorate utilizes the PIC/S GMP Guide (or equivalent) as well as other current guides, guidelines, explanatory notes and recommendations, adopted under the Scheme and available at http://www.picscheme.org, as the basis for inspections and authorization of manufacturers,

(d) the operation of the inspectorate is subject to a system of quality management aimed at ensuring the maintenance of necessary standards.
“How FDA Inspections Could Incorporate Pharmaceutical Inspection Cooperation Scheme PIC/S”

- One of NJ investigators was involved in the PIC/S audit (the qualifying audit) another PI participated in Poland PIC/S seminar.
- Ability to exchange regulatory information with other members.
- ORA Management and the PI will be participating in these Bi-annual meetings and seminars.
Benefits:

- Training Opportunities
- International GMP Harmonization
- International Networking amongst Regulatory Inspectors
- Sharing of Information
- Rapid Alert and Recall System
- Recommendation and Proposals for amendments, updating & improvement of standards
Upcoming Seminars/ Meetings

• Training Seminar for new Inspectors
  January 24-28, 2011 – Ireland

• PIC/S Committee Meeting
  November 7,8 2011 - South Africa

• "Good Pharmaceutical Inspection Practices"
  Training Seminar
  November 9-11, 2011 - South Africa
Q & A Session
• Thank You