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Format of Precursor Chemicals Inspection

Camden Court Hotel, 24th May 2010

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Inspector
IMB

Topics

- Notifications of Inspections
- Planning for Inspection
- The Inspection
- The Inspection Report
- Responses
- Follow-Up

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Notifications of Inspections

- Inspection to commence Q3 2010
- Scheduling based on risk evaluation
- Notification 4-6 Weeks prior to inspection
- Sent to Responsible Officer / Contact Person via email
- Company requested to confirm receipt

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Planning for an Inspection

- Premises
- Quality System/Procedures
- Personnel
- One day inspection
- All relevant personnel available
- Area for paperwork review

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The Inspection

- Opening Meeting
  - Key personnel
  - Purpose & scope of inspection
  - Health & safety considerations
  - Management structure & Quality System
  - Activities of the company
  - Format of the inspection – documentation required / tour
  - Presentation by company (optional)
  - Recent changes / previous inspection issues

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The Inspection

- Documentation Review
  - Quality System (Procedures / Forms / Job Descriptions)
  - Records (Receipt / Supply / Training)
- Tour of facility including security and storage
- Observations / issues discussed as arise

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The Inspection

- Closing Meeting
  - Management and key personnel
  - Summary of findings / deficiencies
  - Possible corrective / preventive actions

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The Inspection Report

- Cover letter summarising inspection
- Introduction and relevant information
- Scope of inspection, inspected areas
- Personnel met
- Inspectors findings and observations
- List of deficiencies observed (Critical, Major & Other)
- Points to be noted, Points requiring clarification
- Issued within 28 days to company

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Company Response

- Summary letter / introduction
- Restate the deficiency cited by the IMB;
- Comment (if necessary)
- State proposed/actual corrective action(s)
- State the target date of completion of the corrective action(s)

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IMB Response

- Letter sent following review of company's response
  - Seeking clarification on responses
  - Stating IMB expectations
  - Stating corrective actions acceptable and inspection closed
  - Company may or may not have to respond

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Follow-Up

- Possible re-inspection to assess implementation of corrective actions from initial inspection
- Interval decided on case-by-case basis
- Next routine inspection based on risk evaluation

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Points to Note

First round of inspections will be……

- Fact-finding
- Open process to assist in educating & assessment of compliances
- Determine the need for formal IMB guidance
- Assist in the development of a proportionate system of inspection, utilising risk-based planning
- Free of charge (initially)
- Subsequently will be linked into the controlled drugs inspection process (incl. fees and logistics)

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Thank you

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