Session 4: Risk assessment for aseptic techniques/practices

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Aseptic Processing Workshop:
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Xellia Pharmaceuticals

- Masters in Microbiology from IIS, Aurangabad
- 34 years in Pharmaceutical industries
- Long Terms:
  - Lupin (14 Y);
  - Strides (13 Y);
  - Wockhardt (2 Y);
  - Xellia (4 Y);
- Short Terms: Hindustan Antibiotic; Almet; Ajanta Pharma; Intas Pharma
  - Projects of sterile formulations & Regulatory guidelines;
  - Techno-commercial activities
  - Implementing cost reduction initiatives.
  - Due diligence / Compliance audits / Regulatory audits & vendor development
Anyone, who don’t Know Risk Assessment / its procedures & Tools?

Any company, that doesn’t perform Risk Assessment/s?

Periodic Reviews, on Risks/Failures (CAPA /Deviation/s) ?

Reassessment of Risk areas (Aseptic practices)?

SOP’s are demonstrable for practice/s?

If YES...
### FACTORS IMPACTING ASEPTIC PRACTICES

**METHODS**
- Established procedures for aseptic practices
- Effective controls on Filtration, Sterilization assurance
- Effective intervention management - Qualified / unqualified
- Cleaning/Sanitation process
- Training Management

**MATERIALS**
- Handling & Movements - within same and different class
- Holding and Storage
- Washing, Depyrogenation of containers & closures
- Sampling /Equipment operating Tools in Grade A

**MOTHER NATURE-ENVIRONMENT**
- Bioburden level
- Utilities (Air/Water) monitoring
- Particulate Matter
- Environment isolates/Micro-organisms controls
- Disinfectants / Cleaning controls

**MEN**
- Gowning
- Cleanroom behaviours
- Practical Trainings & seminars
- Aseptic process knowledge

**MACHINES**
- Cleaning – CIP / SIP
- Holding
- Validation effectiveness
- Integrity throughout product line
- Breakdown maintenance control

**OTHERS**

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### DECODE - ICEBERG

- Knowledge on Risk assessment
- Expertise in Root Cause Implementations
- Culture / Attitude
- Effective QbR

- Awareness to Guidelines & regulatory requirements
- Robust Quality System established through benchmarking

- Voluntary Escalation
- Adequate Training/Competency to all levels

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### WHY STILL WARNING LETTER SITUATION

- Evaluation on risk mitigation plan & control measures
- Culture / Attitude
- Voluntary Escalation
- Adequate Training/Competency to all levels
Thank You