**Root cause analysis – Ishikawa diagram for potential causes of a contaminated product**

Premises & Equipment

 Utilities

Quality control

Environmental Monitoring

Cleaning & Disinfection

**Contaminated Product**

**EFFECT**

Design-flow of products

 No RAB/Isolator

 Material/surfaces

 Drains

Transfer of equipment/materials

 Airlocks

 Decontamination process

 Cleanroom qualification/classification

 Disinfection

 Training & Control of Personnel

 Operation

 Maintenance

 Repairs

Calibration

Cleaning

Age

Cleanroom behaviour

 Water system

 Training

Aseptic processing

Gowning/Handwashing

 Clothing

 Laundry

Numbers in cleanroom

 Heating system

 Direct contact

 Design

Installation information

 Alarms

 WFI

 Trending critical parameters

 Training/expertise in microbiology

 Spec for R**M**’s,components,products

 Bioburden assay

 Sterility test/sampling

 RA for short expiry dates

 Growth promotion for media

Rapid monitoring system (validn)

 EM Program design & control

 Alert/action levels

 Trending

 Continuous monitoring

Sampling (method)

Identification level

Micro monitoring of gowning

Aseptic process simulations

Process simulations tests

 Rotation of disinfectants

 Val studies for use

 Expiry dates

 Sterility

Monitoring for effectiveness

 Efficacy