**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