CRG on the Move

Challenges of EtO Sterilisation and Revalidation

Celli Clews – Technical Manager
CRG have been supplying Cleanroom garments for over 40 years to many industry groups including:

- Pharma Companies
- Medical device
- Hospital Pharmacies

Many of these customers require sterile garments.
Clean Room Garments

Two sites, Sydney (HO and DC) & Melbourne (Processing).

Highly specialised business which prides itself on quality and service.

Seamless transition down to a single processing site.

4 revenue streams
- Garment Processing & Sterilisation (Established)
- Products (Established)
- Managed Training Services (Growing)
- CRG Environmental (Under Development)

Commercial in Confidence
Major challenge - **Capacity**

2 facilities merged into single processing facility.

Chamber volumes fixed /at capacity.

Process already validated at processing facility.

Review the length of the sterilisation cycle.

Therefore **Time** is the critical variable

Focus on reducing the overall cycle time.
Solution

• Shorten routine revalidation cycle and tie this in with the original validation data.
  e.g. Installation Qualification/ Operational Qualification
Challenges

• Ideal temperatures
• Humidity profile
• EtO absorption
• Interruptions to normal production
• Continuity of supply
• People
• Cost
• Temperature profiles were completed for empty and full chambers

• Results showed cold spots below the target of 50°C to 55°C

• Introduction of more steam caused wetting issues, which required trial and error till a balance was found
Challenges

• Humidity loggers placed within each load record the humidity profile of each cycle.

• Challenges presented with wireless units

• ETO concentration levels are readily ascertained from dedicated fixed ETO sensors within the chamber.

• Enabled absorption profiles
• CRG have an in-house laboratory, reduce delays associated with contract laboratory.

• Ability to act on BI failures faster.

• Cost reductions also a factor. Eliminate the need to outsource all testing.

• 4 hour incubation for BIs allow for rapid turnaround of results.
Validation Approach

Revalidation in accordance with ISO 11135
- Half cycle (overkill) method 3 x half cycles

Routine Bio burden monitoring of product as part of Quality Control

Enumerated BIs used utilise Bacillus Atropeheus spores $10^6$. 
• Cycle shorten by 60 minutes sterilisation and 60 minutes in chamber aeration

• Extra cycle per steriliser = 1000 garments/day

• Aeration studies were performed to ensure sufficient clearing of residuals (<1ppm) the result 4 hours (inline with BI incubation)