CRG on the Move

Challenges of EtO Sterilisation and Revalidation

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Clean Room Garments

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)

Challenges

- 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

Challenges

- 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

Considerations

- CRG have a 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

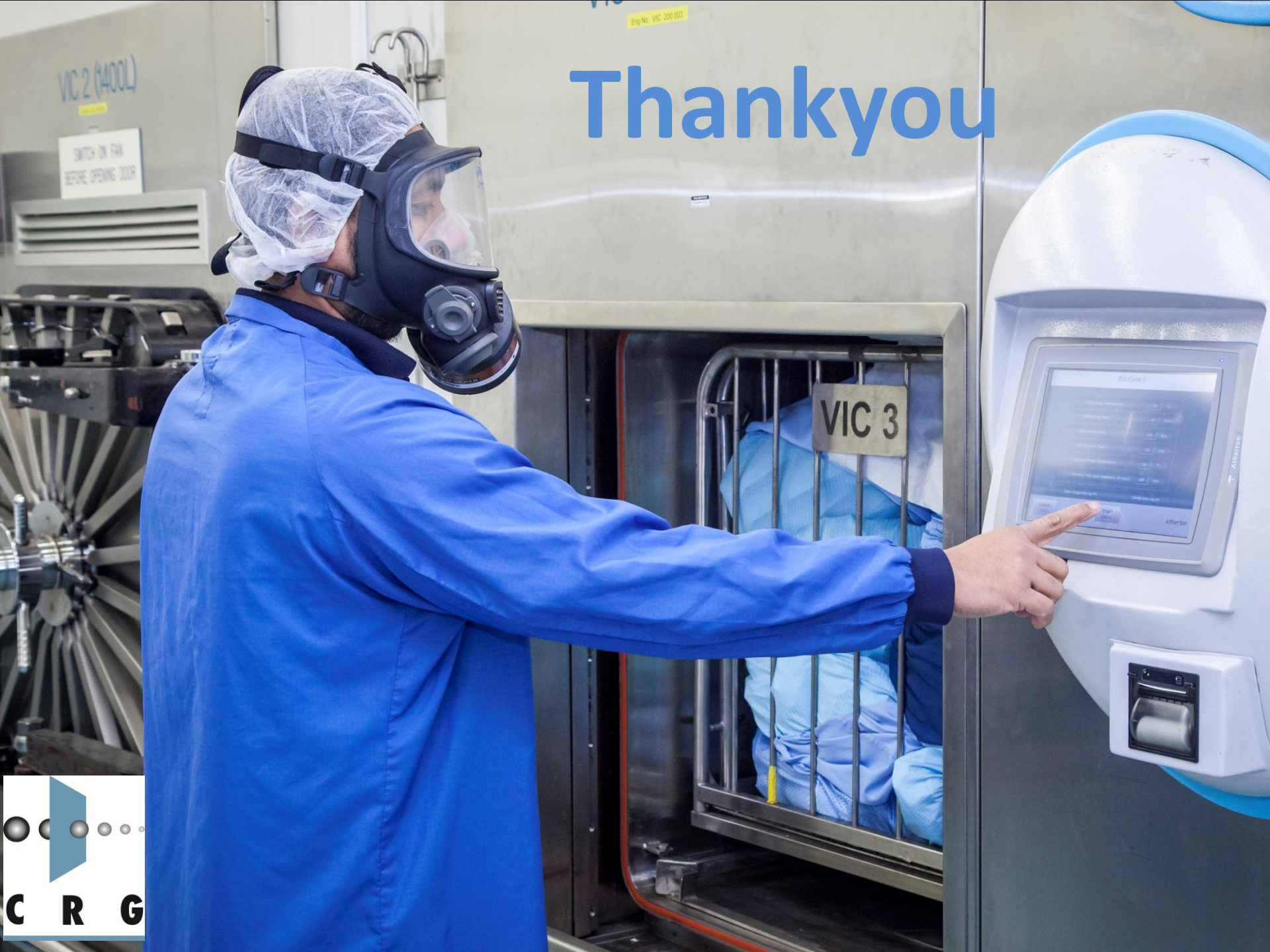
- Half cycle (overkill) method 3 x half cycles

Routine Bio burden monitoring of product as part of Quality Control

Enumerated BIs used utilise Bacillus Atropheus spores 10^6.

Outcome

- 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)


Thankyou
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