

## Why attend?

This Back to Basics seminar is your opportunity to invest yourself in critical aspects of GMP Cleanroom operations.

### Panel of Experts In GMP Cleanrooms

Lessons Learned and GMP Cleanroom Best Practice in:

- o Quality Risk Management
- o Standards
- o Gowning & Behaviour
- o Cleaning
- o Certification & EM

**MEET Supply Chain Vendors  
VISIT the Bio-Pharma Facility**

## Who should attend?

This Back to Basics seminar will be of benefit to:

- Key personnel involved in the preparation process for a GMP Cleanroom Audit.
- Cleanroom users, including Operations, Quality, Engineering and Facilities who want to understand and learn from others involved in best practice GMP Cleanroom operations.
- Supply Chain companies who provide facilities and services to the Life Science industry, including:
  - o Design, Build & Maintain
  - o Gowning & Consummables
  - o Contract Cleaning
  - o Certification & EM

## Irish Cleanroom Society Back to Basics Annual Seminar – 10<sup>th</sup> November 2016

# Impact of Changes in ISO Standards & EU Regulations on GMP Cleanrooms

Experts from a number of EU countries will address the changes and likely impacts during a morning technical session. In the afternoon a panel of experts, including invited guests will address questions from the audience. This will be an interactive session with the focus on the impact of the changes on GMP Cleanrooms.

## Attendance Details

BOOK ONLINE at [www.cleanrooms-ireland.ie](http://www.cleanrooms-ireland.ie)

- The fee for the full day event is: **€50 for ICS members and €100 for non members.**
- The fee includes copies of all presentations, a certificate of attendance, lunch & morning/ afternoon refreshments.
- A number of Vendor tabletops will be there in support of the event.
- The seminar will be held at the **Cork Training Centre - Biopharma Facility** (formerly FÁS), Estuary Business Park, Crosshaven Road, Carrigaline, Cork
- For further information contact ICS Education and Training Convenor, Chris Delaney at:  
+353 86 889 0907 [cdela33@gmail.com](mailto:cdela33@gmail.com)  
For directions please visit: <http://corktrainingcentre.ie/about-us/facilities-and-services/carragline/>



## Impact of Changes in ISO Standards & EU Regulations on GMP Cleanrooms

- ISO 14644 -1 & -2:2015
- EM and integrating Non Viable and Viable Monitoring (ISO 14698)
- EU Biocides Directive
- Update on Annex 1

## GMP Expert Panel (afternoon session)

**Location:**  
**BioPharma Training Facility**  
Carrigaline, Co Cork  
Cork Education and Training Board

**Thursday Nov 10<sup>th</sup> 2016**  
**09:00 – 16:00hrs**