

## QUALITY DEFECTS & RECALL WEBINAR

3RD OCTOBER

10AM-1:10PM

10.00-10:10AM  
(10 MINS)

### WELCOME AND INTRODUCTIONS

Susan Costello, Network Director BioPharmaChem Skillnet

10:10-10:30AM  
(20 MINS)

### QUALITY DEFECTS AND RECALLS OVERVIEW – A FOCUS ON RECALLS

Dr. Michelle Cuffe, HPRA QDR Manager

10:30-10:50AM  
(20 MINS)

### THE INS & OUTS OF RECALL ACTIONS – HPRA EXPECTATIONS

Breda Gleeson, HPRA Market Compliance Inspector

Break- 10:50-11:05

11.05-11.15AM  
(10 MINS)

### QA/RA WORKING GROUP OPPORTUNITIES WITHIN BIOPHARMACHEM IRELAND

Karina Cassidy, Senior Executive, BioPharmaChem Ireland

11:15-11:35AM  
(20 MINS)

### COMMON DEFICIENCIES AND PRACTICAL TIPS FOR RECALLS

Siobhán Nolan, HPRA QDR Inspector, and  
Frances Foley, HPRA QDR Scientific Officer

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11:35-11:45AM  
(10 MINS)

**HPRA EXPECTATIONS FOR EXECUTING MOCK RECALLS**  
Dr. Kevin O'Donnell, HPRA Market Compliance Manager

11:45AM-12:20PM  
(35 MINS)

**ICH Q9(R1) - THE APPLICATION OF THE NEW QRM GUIDANCE TO QUALITY DEFECTS AND OTHER GMP ISSUES.**  
Dr. Kevin O'Donnell, HPRA Market Compliance Manager

12:20-1:00PM  
(40 MINS)

**ASK THE REGULATORS, Q&A**

1:00-1:10PM  
(10 MINS)

**CLOSING REMARKS**  
Susan Costello, Network Director BioPharmaChem Skillnet