A Practical Introduction to Sterile Manufacturing

w/c 16th September –

Birmingham / Leiden – 2 dates / 2 venues Dates TBC

AGENDA

08.30 – 09.00 **Registration with tea/coffee**

09.00 – 09.45 **Introduction to sterile manufacturing**

- What does sterile mean?
- Why do we need sterile products?
- Sterile vs aseptic – are they the same?

09.45 – 10.30 **Introduction to microbiology**

- What is microbiology?
- The bacteria, moulds and yeasts, virology, parasites and TSEs
- Controlling and understanding microbial growth

10.30 – 11.00 **Morning break with tea/coffee**

11.00 – 11.45 **Introduction to cleanrooms**

- What is a cleanroom
- Cleanroom grades and controls
- Design and equipment
- Cleanrooms as a contamination control system
- Cleanroom behaviours

11.45 – 12.30 **Methods of sterilisation**

- Moist and dry heat
- Filtration
- Irradiation and e-beam
- Chemical

12.30 – 13.30 **Lunch**

13.30 – 14.15 **Process manufacturing**

- Common product dose forms
- How to manufacture these dose forms
- Isolators RABS and open filling
- Blow fill seal, freeze drying
- Process simulations, media fills and broth trials

14.15 – 15.00 **Sterility assurance**

- What is sterility assurance?

- Risk based manufacturing
- Determination of sterility

15.00 – 15.30 **Afternoon break with tea/coffee**

15.00 – 15.45 **Sterile manufacturing and the regulations and compliance to GMP**

- Why is there a need for regulations?
- Who regulates the pharmaceutical industry?
- Are you inspection ready?

15.45 – 16.00 **Closing remarks**