Introduction:

Many drugs/APIs or products to be used for the manufacturing of medicinal products require pre-defined conditions for the manufacturing process if they are used to be sterile. To archive sterility of these products it is necessary to implement special technical, organisational and systemic processes to assure the sterility. Knowing and applying the GMP regulations is one of the key elements in the manufacture of medicinal products and medical devices. Particularly in the manufacture of sterile medicinal products, employees have to comply with extensive requirements. Against this background, on one hand a highly qualified system has to be implemented and on the other hand employees have to know the GMP and other requirements and must know how to introduce and to use them in practice.

Cont.

Also Don’t miss our upcoming Events For Next Three Months:

- Overcoming Challenges In Preparing CMC Dossiers.
- Corrective And Preventive Action (CAPA)
- Technical Writing.
- Good Laboratories Practices.

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**Introduction:**

The course will demonstrate what regulatory requirements are to be followed and how to implement these regulations into the daily work. Practical examples and proposals will be given beside discussion of daily problems given by the participants.

The aim of the course is to help answering the question and presenting the concrete transfer of regulatory requirements into practice. Where are the main challenges together with practical difficulties and how can they be solved pragmatically in the manufacturing process by usage of equipment and rooms and a correctly implemented quality system to obtain sterile products. The course will present elements and situations which employees are regularly confronted with. The small group will help the participants in introducing the topics discussed into the daily work and try to give proposals on how employees can implement these requirements into their daily work.

The course is going to focus on any product or substance which is intended to be sterile like Formulations / Solid Dosage Manufacturing, APIs and Finished Products.

It will also be demonstrating how to control and maintain the sterile status of the process.

**Meet Your Expert Coach:**

**Dr. Heinrich Prinz**

Dr. Heinrich Prinz has well acknowledged experience *(nearly 30 years)* of operative, consultative, technical and managerial experience in the highly regulated pharmaceutical industry in many products including sterile products, biotechnological products, genetically modified pharmaceutics and medical devices.

He worked in several pharmaceutical companies as a global head of Quality Management and has successfully passed many FDA audits as well as together with different companies.

Over the last **13 years** he supported as a consultant many different companies in implementing and maintaining of controlled document / quality systems, Including risk management, complaint management, deviation management, CAPA and associated site wide employee training. In addition he has performed FDA Mock inspections briefing and submittal post inspection documents including 483 responses that all were accepted by FDA and other regulatory agencies.

Together with many companies he run a lot of validation processes such as sterile products, bio-pharmaceutical together with the relevant cleaning validations. All of these processes passed successfully the inspections of the regulators.

He executed many third party audits all over the world in the name of the clients in checking GMP compliance of their work/products for the acceptance by the European authorities.

Additionally he is well experienced in implementing combined quality management systems for medical devices and ISO 9001 together with drugs.
FORENOON

Regulatory Requirements For Sterile Manufacturing of API and finished products:
- Definition of the term: Sterile.
- What products must be manufactured sterile and its contribution to receive sterile finished products?
- What are the regulatory requirements?
  - FDA.
  - Europe.
  - Schedule M Part I-A.
  - PDA.
  - EN ISO 14644 - Series.
- How to implement the WHO Regulation on sterile products requirements?
- What are the basic requirements for sterile manufacturing?
- Responsibilities in sterile manufacturing.

The New Annex 1 and changed ISO 14644-1:
- Manufacturing of API & Finished Products under the regulatory requirements for sterile products.
- Annex 1 as a global requirement for the sterility assurance:
  - Content of the new Annex 1 of the GMP guideline:
  - What has been changed from the old version?
  - Practical aspects on the changes.
  - How to adopt the changed requirements?
  - What are the main differences?
- ISO 14644-1 as a requirement for clean rooms:
  - Content of the changed ISO 14644-1
  - What has been changed from the old version?
  - Practical aspects on the changes.
  - How to adopt the changed requirements?
  - What are the main differences?
- How to implement the regulatory requirements.
- Special requirements on implementing the requirements: Practical aspects from the participants.
- Warning letters.

Small group work:
Discussion on implementing of the rules & discussing of examples:
- Risk Analysis.

Activities:
Delegates of the course will be encouraged to actively participate by sharing their own experiences and applying the lessons learnt from the presentations to own real-life situations in discussions.

AFTERNOON

Building up the awareness for sterile manufacturing.
What are the different methods to receive sterility during manufacture of products:
- Sterility via different final sterilization processes:
  - Heat sterilization.
  - Based on radiation / terminal.
  - Chemical sterilization.
  - Aseptic processing
- From API to aseptic finished products to maintain sterility:
  - Handling of sterile API in sterility production for finished products.
  - How to assure aseptic processing?
  - Methods for the shipment and for receiving aseptically produced products.

Small Group Work:
Discussion of the pro and cons of the different sterilization methods:
- Risk considerations.

The contribution of the different aspects to maintain sterility:
- The contribution of the personnel:
  - Gowning process.
  - What gowning to be taken?
  - What about visitors? To be taken into these areas?
  - Behavior in sterile environment.
- The contribution of rooms and buildings / technical attributes:
  - Introducing of different classification.
  - Pressure system.
  - Filtering systems
  - Control of filters
  - Hygienic aspects.
- Sterility maintenance:
  - How to demonstrate / observe sterile manufacturing to inspectors/auditors during production?
  - Room cleaning to maintain the sterile status.

Small group work:
- Questions about the different contributions of the departments.

Benefits from the course:
The delegates will learn what the basic requirements are coming from the regulatory and what are the contributions of the different topics to maintain the status.

By exchanging of their knowledge during small group works the participants will discuss on the problems to maintain the sterile status.

A well designed and described management system together with a thorough training of the personnel has to be implemented to relay on the main topics for the assurance of a sterile product. The delegates will learn about the new requirements and the expectations of the regulators and clients.
**FORENOON**

- Technical and practical aspects for sterile manufacturing.
- The clean rooms requirements for aseptic processing against the barrier systems:
  - What are the basis for clean room requirements for the different kinds of processing:
    - Differences in technology.
    - Aseptic versus barrier system.
  - Blow filled seal.
  - Requirements for final sterilization.
  - Aspects on validation of the different processes / Isolators.
  - Validation of sterile packaging for API & Finished.
- Aseptic process simulation:
  - Media Fill Execution and special aspects like interventions etc.:
    - Environmental Monitoring (EM).
    - Monitoring of rooms, equipment.
    - Monitoring of personnel.
  - How to handle failures during aseptic filling.
- Technical aspects:
  - HVAC system to receive and maintain micro-biologically controlled environment.
  - Media fill for aseptic processing for finished products.
  - Water for injection:
    - Manufacturing.
    - Quality control.
  - Qualification of clean rooms.
  - Validation of the sterilisation process.
  - Cleaning of clean rooms.
  - Sampling of clean rooms.
- Small group work:
  - Audit observations / examples from the participants.
- Activities:
  Delegates of the course will be encouraged to actively participate by sharing their own experiences and applying the lessons learnt from the presentations to own real-life situations in discussions.

**AFTERNOON**

- Quality control of rooms and products sampling and monitoring of rooms:
  - Hygiene master plan.
  - Hygiene concept:
    - Cleaning with sterile agents.
  - Control of the sterile manufacturing:
    - Performing of the sterility and environmental testing.
  - Monitoring of the room:
    - Micro-biological / surface testing.
    - Air sampling.
  - Sampling of personnel.
  - Handling of samples.
  - How to handle OOS/MDD results.
- Sampling and testing of the product:
  - Performance of sterile sampling.
  - Testing of components & containers.
  - Micro-biological testing.
  - Handling of OOS in micro-biology / of micro-biological data.
  - Container closure testing.
  - Visual inspection.
- Small group work:
  - OOS in micro-biological test results.
- Benefits from the course:
  The delegates will learn on one hand the technical and practical aspects on the manufacturing of sterile products and on the other hand the sampling and testing of sterile samples.

  Based on practical examples from the speaker and the participants problems of the understanding how to maintain the environmental conditions will be discussed. On the examples given based on the audits performed the training will enhance the knowledge of the participants in how to behave and demonstrate the sterile conditions.

  Quality control methods besides the sampling are important to demonstrate the sterility of the product. During the seminar it will be discussed how to execute testing and what failures might occur. To demonstrate sterility of the process and the product any deviation in testing and sampling has to be thoroughly investigated and discussed before the release of the product.

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**Programme Schedule for two days**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>09:30 am</td>
<td>Registration &amp; Breakfast</td>
</tr>
<tr>
<td>10:00 am</td>
<td>Course Commences</td>
</tr>
<tr>
<td>11:30 am - 11:45 am</td>
<td>Tea Break</td>
</tr>
<tr>
<td>01:00 pm - 02:00 pm</td>
<td>Lunch</td>
</tr>
<tr>
<td>03:30 pm - 03:45 pm</td>
<td>Tea Break</td>
</tr>
<tr>
<td>05:30 pm</td>
<td>Course Ends</td>
</tr>
</tbody>
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Yes! Please register the following delegates for

**STERILE PRODUCTION & STERILITY ASSURANCE**

Featuring in Following Countries

FLAT USD $500/- Per Delegate

<table>
<thead>
<tr>
<th>Country</th>
<th>Date</th>
<th>Hotel</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.A.E</td>
<td>16th / 17th October 2017</td>
<td>5 * Hotel - U.A.E</td>
</tr>
<tr>
<td>UK</td>
<td>19th / 20th October 2017</td>
<td>5 * Hotel - U.K.</td>
</tr>
<tr>
<td>Bangladesh</td>
<td>23rd / 24th October 2017</td>
<td>5 * Hotel - Dhaka</td>
</tr>
</tbody>
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**Documentations / Course Material:**

Attendees will not get any book or CD. IBC will give soft copy of the course material in pen-drive only.

**Payment Policy:**

Payment in full is required in advance or at the time of registration. This Registration Fee includes luncheon, refreshment and conference/workshop materials.

**IBC Cancellation, Postponement and Substitution Policy:**

- You may substitute delegates at any time. IBC does not provide refunds for cancellations.
- For cancellations received in writing more than seven (7) days prior to the Workshop you will receive a 100% credit to be used at another IBC conference for up to one year from the date of issuance.
- For cancellations received seven (7) days or less prior to an event (including day 7), no credit will be issued. In the event that IBC cancels an event, delegate payments at the date of cancellation will be credited to a future IBC event. This credit will be available for up to one year from the date of issuance.
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- IBC is not responsible for any loss or damage as a result of a substitution, alteration or cancellation/postponement of an event. IBC shall assume no liability whatsoever in the event this Workshop is cancelled, rescheduled or postponed due to a fortuitous event, Act of God, unforeseen occurrence or any other event that renders performance of this Workshop impracticable or impossible. For purposes of this clause, a fortuitous event shall include, but not be limited to: war, fire, labor strike, extreme weather or other emergency.
- Please note that speakers and topics were confirmed at the time of publishing, however, circumstances beyond the control of the organizers may necessitate substitutions, alterations or cancellations of the speakers and/or topics. As such, IBC reserves the right to alter or modify the advertised speakers and/or topics if necessary.

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**Registration Form**

Yes! Please register the following delegates for

**STERILE PRODUCTION & STERILITY ASSURANCE**

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