Quality Assurance in Practice: Good Manufacturing Practice and Quality Control

Objective

It is impossible to imagine any industrial branch, even service industries, without a quality assurance system. Therefore it’s all the more important to deal with quality assurance as early as possible, in order to be well prepared when starting a career. Quality assurance is a system companies use to review production systems, products and services to ensure consistent quality results by preventing and identifying weaknesses as well as inconsistencies at a very early stage in the service or production process.

In the manufacture of pharmaceutical products, quality assurance is realised by implementing Good Manufacturing Practice (GMP) throughout the whole lifecycle of a product from the early stage of development throughout production to final quality control.

Description

This one-day course will give a comprehensive overview on the concept of quality assurance in the framework of the pharmaceutical industry, including fundamental aspects and tools applied in practice, with an emphasis on GMP. Modern approaches of risk assessment will be addressed just as the implementation of CAPAs (corrective and preventive actions), dealing with OOS (out of specification) results and realizing change control in a fixed process.

Also data integrity is an important issue of the course. Practical units at the end of the course will give participants the chance to practically implement the knowledge acquired on the example of case studies.

The content of this course is readily transferable to all GxP aspects, e.g. GLP (Good Laboratory Practice), GDP (Good Distribution Practice) etc.

In details the course will deal with:

- the need for and origin of quality assurance
- the concept and definition of quality
- the regulatory key players and requirements
- the applied quality standards by using the example of GMP
- the main pillars of a quality assurance system
- the modern tools in quality assurance (risk analysis, CAPA, change control, OOS….)
- the data integrity
- the foresight into expected future development

Organizational Information

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<thead>
<tr>
<th>Language</th>
<th>English</th>
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<tbody>
<tr>
<td>Target group</td>
<td>Doctoral candidates at all stages and Postdocs from Natural and Life Sciences</td>
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<tr>
<td>Date</td>
<td>Friday, 30 November 2018, 9:00 – 17:00</td>
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<td>Registration</td>
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