How to Overcome the Challenges in Biologics Development & Quality Control

The great increase in the use of biologics has made them a growing concern in the pharmaceutical industry. For biologics to be successful, manufacturers must ensure their quality. This article provides a comprehensive overview on how to overcome the challenges in biologics development, as well as quality control. It highlights the various types of biologics, workflow of biologics development, and regulatory compliance.

Types of Biologics

<table>
<thead>
<tr>
<th>Product</th>
<th>Development Process</th>
<th>Clinical Development</th>
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<tbody>
<tr>
<td>Small Molecules</td>
<td>High Production Costs, e.g., pH, temperature, light</td>
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Workflow of Biologics Development

- Product Research: Identification of potential biologics and their development.
- Process Development: Optimization of the manufacturing process.
- Clinical Development: Testing of the biologic in human subjects.

Regulatory Compliance

10-18 years

Biologics Development & Quality Control: Come with a Number of Challenges...

- Challenges to meet the right industrial standards
- Difficult to achieve required regulatory endpoints
- Complete the regulatory
- Subjeck to evolving regulations

How Does Merck Support Biologics Development & Quality Control?

- To prevent contamination, Merck has... (details not visible in image)
- To address reference standards challenges, Merck has... (details not visible in image)
- To fine more resources for method development, Merck uses... (details not visible in image)
- To support customers through the regulatory maze, Merck offers... (details not visible in image)

Meet Merck's Life Science Brands

- MilliporeSigma
- Sigma-Aldrich
- EMD Millipore

- R&D in... (details not visible in image)

Tackle biologics development and quality control now! Benefit from Merck's expertise and check out its latest educational content and products today.