INTERNATIONAL SUPPLY CHAIN
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Triggers:

- M&A
- Pricing pressures
- Development and clinical cost/capability
- Geographical expansion
- Availability of skillset or raw material
- Regulatory environment
- Companies in Emerging Markets growing stronger

Globalisation is set to increase:

- Many global companies have manufacturing infra spread over 3 or 4 continents
- M&A activity = diversification of supply chain
- Cost cutting in pharma = outsourcing
- Cost pressures = move towards “low cost” countries
- Capability of manufacturers in developing/emerging countries
- Diversification of new product development
- Regulatory (GCP, GLP, GMP…) environment convergence
- Difficulty in moving sites for complex products

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### Challenges:

<table>
<thead>
<tr>
<th>Challenge</th>
<th>Issue</th>
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<tbody>
<tr>
<td>Different regulatory (GCP, GLP, GMP,...) environment</td>
<td>• Confusion</td>
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<tr>
<td>One global quality standard</td>
<td>• While catering to several different markets</td>
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<td>Difficulty in keeping infrastructure targeted to specific markets</td>
<td>• Efficiency</td>
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<td>Management of outsourcing in ‘remote’ locations</td>
<td>• Cost cutting/resources</td>
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<td>New classes of products becoming multisource</td>
<td>• Biologics</td>
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<td>Integration post merger/acq</td>
<td>• Different systems</td>
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### Tackling these challenges:

We already work in the most regulated business in the world, so we are best placed to tackle these complex challenges

- Build TRUST between regulatory agencies
- Harmonize regulations and enforcement
- Effective management of outsourcing
- Reinforce the benefits of one global quality standard
- ‘Competition’ between geographies
- **Balance** between level of quality required to be built into a pharmaceutical product and the price one is willing to pay for it