



## Preparing CMC Submissions in CTD Format From IND to NDA

### 2-Day Regulatory/Chemistry Course Outline

DS = Drug Substance

DP = Drug Product

<b>DAY 1 REGULATORY M. Foster</b>		
<b>DAY/Time</b>	<b>Topic</b>	<b>Guidelines/Resources</b>
9:00-10:30 Section 1A	<b>Introduction:</b> <ul style="list-style-type: none"> <li>▶ Overview of the CTD</li> <li>▶ What's New in the CTD</li> <li>▶ Module 3 and Module 2, Quality Overall Summary</li> <li>▶ Writing CTD Quality submission-ready reports</li> <li>▶ Tips for preparing submissions</li> <li>▶ The eCTD</li> </ul> <b>DS Characterization (S.1, S.3)</b>	<b>ICH M4Q</b>  <b>Agency experience in US and Europe</b>  <b>The SMART process of preparing submissions</b>  <b>ICH Q3A, Q3C</b>
<b>10:30-11:00</b>	<b>Break</b>	
11:00-12:30 Section 1B	<b>DS Manufacture (S.2, S.6)</b> <b>Pharmaceutical Development (P.2)</b> <b>DP Manufacture (P.1, P.3, P.7)</b>	<b>FDA guidance for DS, DP</b>  <b>Other regional guidelines</b>
<b>12:30-1:30</b>	<b>Lunch</b>	
1:30-3:00 Section 1C	<b>Analytical - DS and DP (S.4, S.5, P.4, P.5, P.6)</b>  <b>Stability – DS and DP (S.7, P.8)</b>	<b>ICH Q6A Specifications</b> <b>Q3B DP Impurities</b> <b>Q2A, Q2B Meth Validation</b> <b>Q1A – Q1F Stability</b> <b>Regional Guidelines</b>
<b>3:00-3:30</b>	<b>Break</b>	
3:30-5:00 Section 1D	<b>Appendices (A.1-A.3, R.):</b> <ul style="list-style-type: none"> <li>▶ Facilities and Equipment</li> <li>▶ Adventitious Agents</li> <li>▶ Novel Excipients</li> <li>▶ Regional Requirements</li> </ul> <b>Post-Approval Changes</b>	<b>Regional Guidelines</b>



# CTD Quality Consulting

Helping the Pharma Industry Stay Current with CMC

<b>DAY 2 CHEMISTRY M. Chorghade</b>		
<b>DAY/Time</b>	<b>Topic</b>	<b>Guidelines/Resources</b>
<b>9:00-10:30 Section 2A</b>	<b>Introduction DS Characterization</b>	<b>ICH Q3A, Q3C Regional guidelines</b>
<b>10:30-11:00</b>	<b>Break</b>	
<b>11:00-12:30 Section 2B</b>	<b>DS Manufacture Pharmaceutical Development DP Manufacture</b>	<b>FDA guidance for DS, DP ICH Q8 Other regional guidelines</b>
<b>12:30-1:30</b>	<b>Lunch</b>	
<b>1:30-3:00 Section 2C</b>	<b>Analytical - DS and DP Stability – DS and DP</b>	<b>ICH Q6A Specifications Q3B DP Impurities Q2A, Q2B Meth Validation Q1A – Q1F Stability Regional Guidelines</b>
<b>3:00-3:30</b>	<b>Break</b>	
<b>3:30-5:00 Section 2D</b>	<b>Drug Master Files Labeling Nomenclature Q&amp;A</b>	<b>Regional Guidelines</b>