



42nd
Annual Meeting

Introduction to CTD Submission-Ready Documents: Module 3



Philadelphia 2006

Michelle Herrera Foster,
Ph.D.

Regulatory Affairs Consultant
CTD Quality Consulting



CTD Quality Consulting

Learning objectives

At the conclusion of this session, participants should be able to:

- To learn to write submission-ready reports using a modular format to address regional differences.
- To evaluate the design and use of customized templates in cross-functional teams to write and review submission-ready reports and to perform gap analysis and track action items for the marketing application.

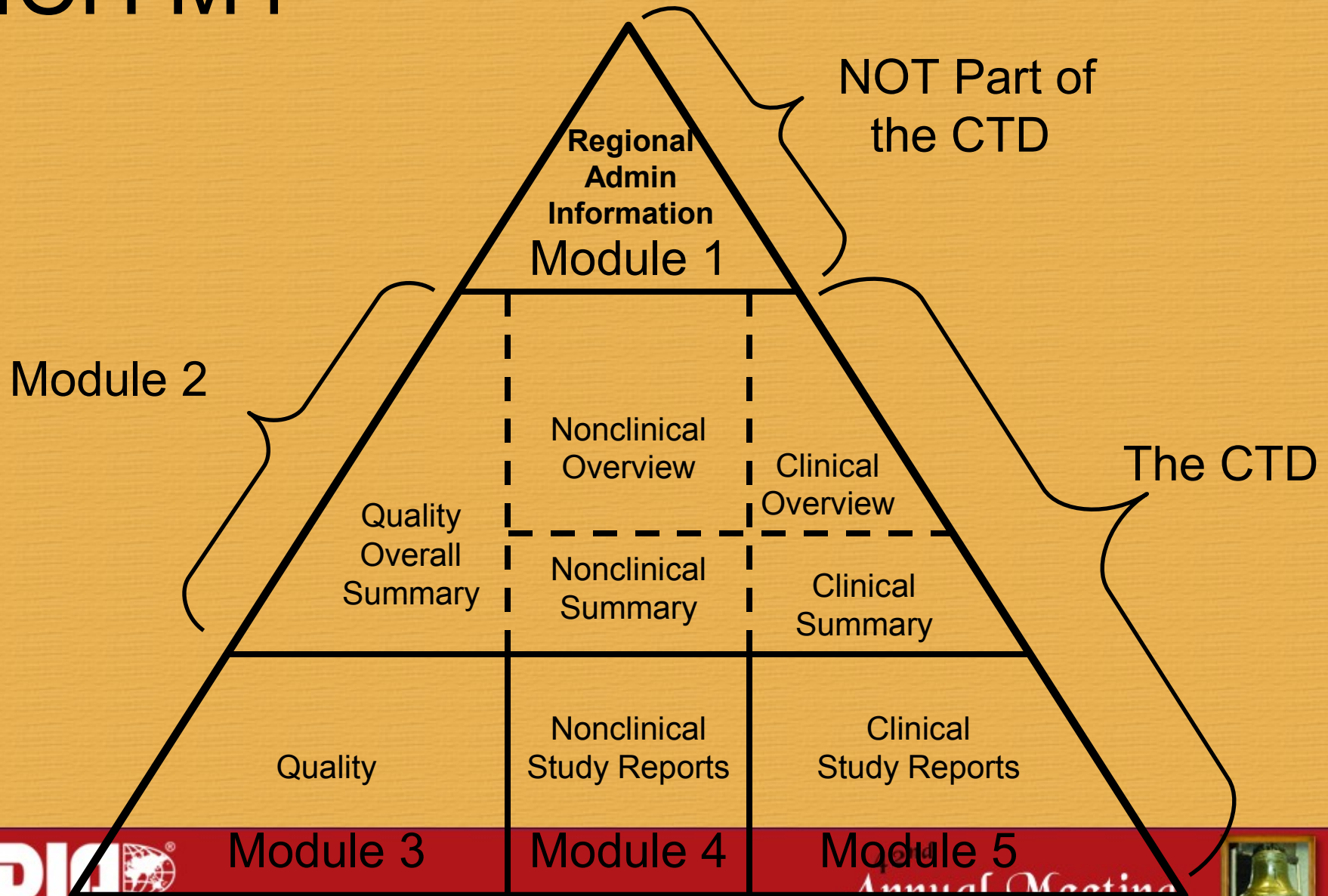


Topics

- Introduction to the CTD and Module 3
- Building the NDA from the IND
- Submission-ready reports in Module 3
- Using CTD templates to assist authors



ICH M4



Advantages of the CTD Format

- Harmonization of drug applications
- Provides standards to prepare submission-ready documents in the IND phases
- Standardization assists project management, information management, and gap analysis
- Facilitates drug development planning
(IND → NDA)
- Facilitates life cycle management



The CTD – Quality Sections

Module 3

3.1 Table of Contents

3.2 Body of Data

3.2.S DRUG SUBSTANCE

3.2.P DRUG PRODUCT

3.2.A Appendices

3.2.A.1 Facilities and Equipment (Biotech)

3.2.A.2 Adventitious Agents Safety Evaluation

3.2.A.3 Novel Excipients (see 3.2.S format)

3.2.R Regional Information

3.3 Literature References



Module 3 Drug Substance (DS)

Section	Title	Functional Area
3.1	Table of Contents	
3.2	Body of Data	
3.2.S	Drug Substance	
3.2.S.1	General Information	DS Characterization
3.2.S.2	Manufacture	DS Manufacture
3.2.S.3	Characterization	DS Characterization
3.2.S.4	Control of DS	Analytical
3.2.S.5	Reference Standard	Analytical
3.2.S.6	Container Closure	DS Manufacture
3.2.S.7	Stability	Stability



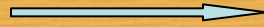
Module 3 Drug Product (DP)

Section	Title	Functional Area
3.2.P	DRUG PRODUCT	
3.2.P.1	Description & Composition	DP Manufacture
3.2.P.2	Pharmaceutical Dev't	DP Manufacture
3.2.P.3	Manufacture	DP Manufacture
3.2.P.4	Control of Excipients	Analytical
3.2.P.5	Control of Drug Product	Analytical
3.2.P.6	Reference Standard	Analytical
3.2.P.7	Container Closure System	DP Manufacture
3.2.P.8	Stability	Stability



Building the NDA from the IND

CTD



IND (Phase 1)

- Module 2 Summaries
- Mfg Description, flow chart, mfg development
- Process Validation
- Methods Validation
- Container Closure
- Stability
- A.1 Facilities/Equipment
- *Complete details*

- Not required (except Can)
- Detailed flow chart, mfg development summary
- Only viral safety
- Critical parameters
- Brief description
- Support duration of study
- Not required
- *Focus on safety*



Submission-Ready Reports

- Build the marketing application from Ph 1 to NDA and post-marketing
- The modular approach to writing submissions
- Each section/attachment is a technical report, or a section within the report
- Meet eCTD granularity rules
- More efficient use of resources, expedites submissions, less cost and stress to the organization



Examples of Module 3 Reports

- Characterization
- Formulation Development
- Manufacturing Development
- Method Validation
- Justification of Specifications
- Process Validation
- Stability Reports
- Stress Studies
- Container-Closure Evaluation

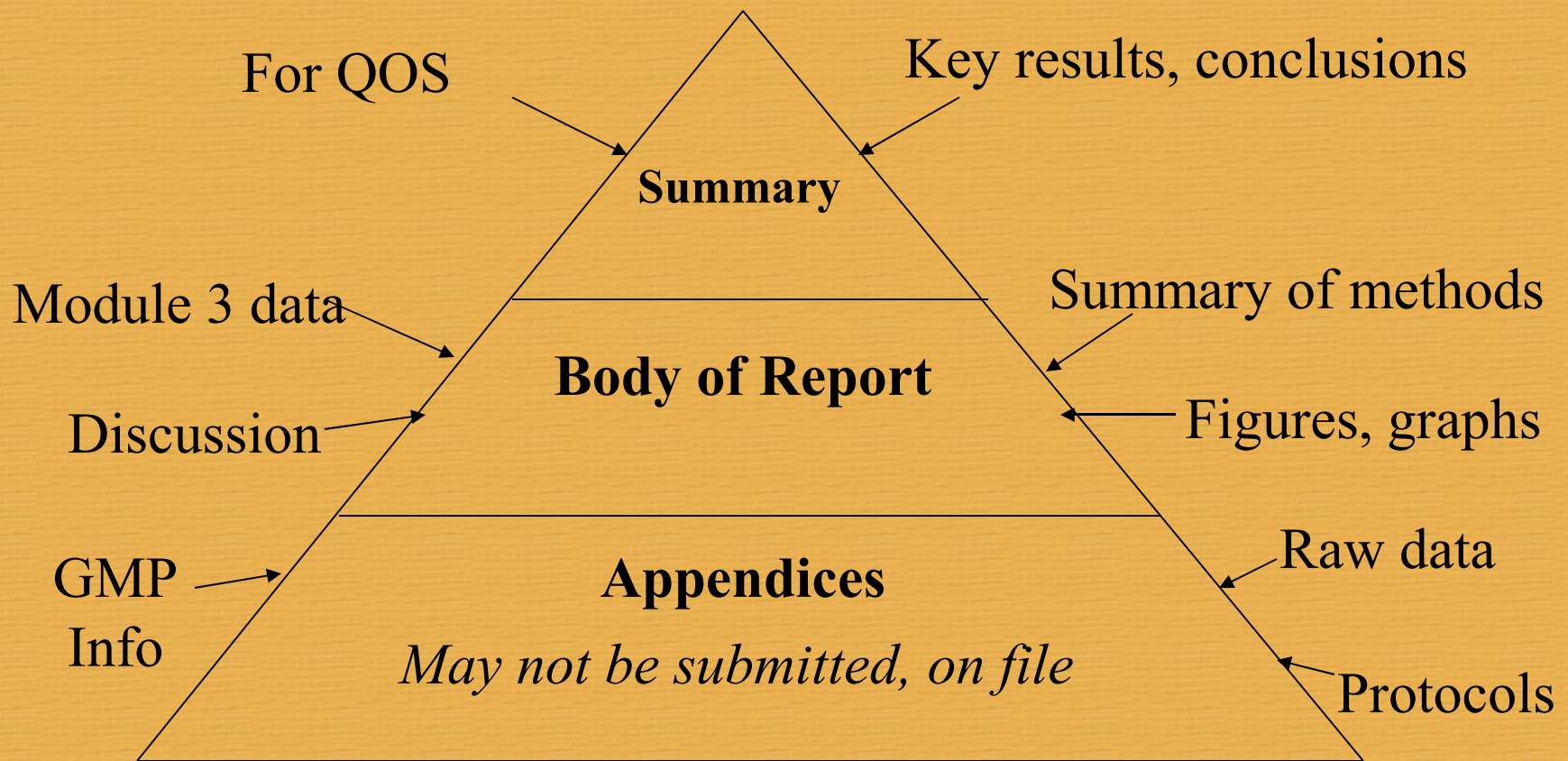


Category of Reports

1. Reports submitted in full, *e.g. method validation report*
2. Summary reports without appendices, *e.g. process development report*
3. High level summaries
4. Reports on file for inspection



Levels of Submission-Ready Reports



Writing Submission-Ready Reports

- Amend, modify, replace portions of the report throughout development
- Use subsections for regional information that can be tailored prior to submission
- Keep consistency of format and terminology between reports
- Cross-references added for the submission



CTD Templates

- Define content and format for each section, enabling gap analysis
- Address CTD, ICH, agency guidance
- Address agency agreements
- Customized for each product
- May be expanded into model reports



Conclusions

- ✓ Submission-ready reports improve efficiency throughout development.
- ✓ The CTD content templates assist authoring and approval of strategy, gap analysis, and project management
- ✓ Submission planning and quality are keys to success and rapid approvals.



References

ICH: International Conference on
Harmonization www.ich.org

FDA: Food and Drug Administration (U.S.)
www.fda.gov

EMA: European Medicinal Evaluation
Agency (EU, Europe), www.emea.eu.int



Panel Contacts

Michelle@ctdquality.com 978-356-0872

www.ctdquality.com

Pcafiero@rdg.boehringer-ingelheim.com

