May 25, 2004

NOTICE

Our file number: 04-110632-96

Revised Quality Guidances on the Implementation of the Common Technical Document for Biological Products

The Biologics and Genetic Therapies Directorate (BGTD) is pleased to announce the release of the following updated guidance documents and electronic summary template on the use of the *International Conference on Harmonisation* (ICH) Common Technical Document (CTD) format for preparing the Quality information, in support of a drug submission for a biological (Schedule D) product for human use, filed in Canada pursuant to Part C of the *Food and Drug Regulations*- Divisions 1, 1A, 2, 4, 5, and/or 8:

Updated Quality Guidances for Industry: (This set of guidances supersede the draft versions dated June 25, 2003. The minor changes were primarily to incorporate revisions made in the *ICH CTD-Quality Questions and Answers/ Location Issues* document (July 17, 2003), as well as, to address comments received to-date on the previous draft versions of these guidances. These guidances are now considered **final** and should be used to prepare drug submissions in the CTD format.)

- *Preparation of the Quality Information for Drug Submissions in the CTD Format:* ***Biotechnological/ Biological (Biotech) Products***
- *Preparation of the Quality Information for Drug Submissions in the CTD Format:* ***Blood Products***
- *Preparation of the Quality Information for Drug Submissions in the CTD Format:* ***Conventional Biotherapeutic Products***
- *Preparation of the Quality Information for Drug Submissions in the CTD Format:* ***Vaccines***

Electronic Quality Summary Template: (This template is now considered **final** and for implementation with all Schedule D products, where appropriate. It is identical in content to the June 25, 2003 version.)

- ***Certified Product Information Document (Schedule D drugs)*** (*CPID (Schedule D drugs)*)

Note: Since these Health Canada guidances also contain the ICH CTD-Quality guidance within them for Module 2.3 Quality Overall Summary and Module 3.2 Quality, document divisions (i.e. start and end bars) have been included within the guidance to segregate these elements and to assist with navigation through the document. In order to ensure that the proper CTD format is obtained, users are advised to print the guidance as a pdf file (instead of a html file).

With the availability of these Quality guidances and template, as well as, the Health Canada guidances, *Preparation of New Drug Submissions in the CTD Format*, and *Guidance for Clinical Trial Sponsors- Clinical Trial Applications*, this allows sponsors to use the CTD format for essentially all types of drug submissions filed to BGTD during the life cycle of a biological product (Schedule D drug) and/or a drug/drug or drug/device combination of which the drug component is a Schedule D drug. Regardless of the format of the original or previously-related submissions, the CTD format should now be applied to the following: New Drug Submissions (NDSs), Supplemental New Drug Submissions (SNDSs), Notifiable Changes (NCs), Biological Drug Identification Number Applications (DIN-Bs) and their amendments, Clinical Trial Applications (CTAs), and their amendments (CTA-As).

Note that separate guidances are also under development for DIN-Bs and Radiopharmaceutical (Schedule C) products. The DIN-B and Radiopharmaceutical guidances and the new *CPID (Schedule C drugs)* template (in CTD format) will be made available as soon as possible. However in the meantime, the CTD format may also be used for these types of submissions and products. Please consult with the Submission Management Division, Centre for Policy and Regulatory Affairs (SMD, CPRA), and the appropriate product-line division of the Biologics and Radiopharmaceuticals Evaluation Centre (BREC) within BGTD, for further information prior to filing.

Although these guidances and templates are considered final, they are subject to further changes, as appropriate. For example, Health Canada is currently considering the addition of the following text under the scope of the *Preparation of the Quality Information for Drug Submissions in the CTD Format:* ***Blood Products*** guidance (section 1.2): "This guidance also applies to human or animal blood or blood component products intended for transfusion, which are subjected to manufacturing steps using for example, pathogen reduction technologies or chemical treatments, whereby raw materials (e.g. chemicals) are further introduced to the biological source material, possibly resulting in structural, physicochemical, and/or biological changes of the product. These manufacturing steps may subsequently include purification or elimination steps, and appropriate controls to ensure product safety, quality, and efficacy, as a consequence. Platelet-inactivated blood, solvent-detergent-treated blood, psoralen-treated blood, and blood substitutes are a few examples." This proposal will be undergoing further consultation in the months ahead. In the interim, please contact the Submission Management Division, Centre for Policy and Regulatory Affairs (SMD, CPRA), and the Blood, Tissues, and Organs Division of the Biologics and Radiopharmaceuticals Evaluation Centre (BREC) within BGTD, for further guidance.

Implementation Dates and Acceptable Formats During the Transition Period

As previously announced (in the July 30, 2001, September 12, 2001, and June 25, 2003 Notices), Health Canada adopted **July 1, 2003**, as the official date by which applicants should use the CTD format for newly filed drug submissions for human use.

Note: During the transition period, a certain level of discretionary flexibility pertaining to format changes may be exercised on the part of BGTD, during the screening process. However, this flexibility does not extend to content requirements, since this is unchanged with the migration towards

CTD-formatted submissions. As a matter of good guidance practices, any updates to CTD-related filing requirements will only be introduced following advance notice and they will not be applied retroactively to submissions pending review.

The applicant should use the most appropriate Quality guidance(s) and template(s), based upon for example, the source or starting material(s), the manufacturing method, the inherent safety, and/or other unique considerations specific to their product. The applicant should also refer to other general Health Canada guidances, with respect to filing certain types of drug submissions in the CTD format and any extra guidance which may be provided as a *Questions and Answers* document, posted on either the TPD/ BGTD and/or ICH website(s)[1]. For further information, please contact the Submission Management Division, Centre for Policy and Regulatory Affairs (SMD, CPRA), and the appropriate product-line division of the Biologics and Radiopharmaceuticals Evaluation Centre (BREC) within BGTD.

In particular for CTAs whereby an electronic QOS is not provided as a review tool for the evaluator, during CTD and eCTD implementation, an applicant will be encouraged to continue using an existing Canadian Quality Summary electronic (Wordperfect) template, such as the *Quality Information Summary- Biologicals (QIS-B)*, either in place of or in addition to a Module 2.3 Quality Overall Summary (QOS) document, in order to afford review efficiencies. This is due to the short review times defined for CTAs. In the case whereby an existing Canadian Quality Summary is used, the associated *Certified Product Information Document* (*CPID*) template version should also be used (if required) and provided in Module 1.4.1, according to the CTD format. The use of a Canadian Quality Summary document in Module 2.3, with supporting CTD-formatted Quality information in Module 3, (and a *CPID* in Module 1.4.1, if required), is considered to be an acceptable "mixed Canadian-CTD format" during the transition. The applicant should consult with the SMD, CPRA, if necessary.

To further assist the applicant during the transition phase, this notice includes several Appendices which compare the location of Quality information between the current Canadian versus CTD formats for a NDS (and other submission types, as appropriate), to either help the applicant transfer information from a previously prepared submission into a CTD-formatted new submission, to aid with cross-referencing from a CTD formatted submission to a previous related-submission in the "old" format, or to assist with cross-referencing Quality information across modules in a "mixed Canadian-CTD" formatted submission. This guidance is being republished and is identical to that previously published under the June 25, 2003 Notice for Biological Products. The Appendices supplement the product-specific guidances as follows: Appendix A: Common Sections/ Modules for all Schedule D drugs; Appendix A-1: Specific Drug Substance Section/ Module for Biotechnological/ Biological (Biotech) Products; Appendix A-2: Specific Drug Substance Section/ Module for Blood Products; Appendix A-3: Specific

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[1] http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/
http://www.hc-sc.gc.ca/hpfb-dgpsa//bgtd-dpbtg/
http://www.ich.org

Drug Substance Section/ Module for Conventional Biotherapeutic Products; Appendix A-4: Specific Drug Substance Section/ Module for Vaccines; Appendix B: Radiopharmaceutical (Schedule C) products.

Note: An applicant is not expected to reformat a previously-related submission into the CTD format for cross-referencing purposes. However, the cross-referencing should be specific and clear enough for the evaluator to easily locate the information.

Contacts

Questions relating to the specific documents, such as this notice and/or the BGTD Quality guidances and template referred to within this notice, should be submitted to:

Biologics and Radiopharmaceuticals Evaluation Centre
Biologics and Genetic Therapies Directorate
Fax: (613) 948-3655
e-mail: BGTD_BREC_Enquiries@ hc-sc.gc.ca

Questions concerning general filing requirements for CTD formatted submissions and the possible need for a pre-submission meeting should be directed to:

Submission Management Division
Centre for Policy and Regulatory Affairs
Biologics and Genetic Therapies Directorate
Fax: (613) 957-0364
e-mail: SMD_Submissions@hc-sc.gc.ca

Appendix A: Location of Quality Information in the Current Canadian Versus CTD Formats: Common Sections/ Modules for all Schedule D drugs

***QIS-B-rDNA/ MAbs*; *QIS-B-BLD*; *QIS-B-Conventional Biotherapeutic Products*; and *QIS-B-VAC* in Current Canadian Format**		**Module 2.3 *QOS (Biotech); QOS (Blood Products); QOS (Conventional Biotherapeutic);* and *QOS (Vaccines)* in CTD Format**	**Module 3.2 Body of Data in CTD Format (cross-references to other related subsections)**	
Section#	**Section Name**	**Module#**	**Module#**	**Module Name**
Part 1 of 4:				
G.	GENERAL INFORMATION			
G.1	SUBMISSION SUMMARY	INTRODUCTION		
	Brand Name	INTRODUCTION		
	Proper or Common Name	INTRODUCTION		
	Submission Sponsor	INTRODUCTION		
G.2	DRUG SUMMARY			
	Therapeutic Classification	INTRODUCTION		
	Code Name or Number	INTRODUCTION		
	Dosage Form(s)	INTRODUCTION		
	Strength(s)	INTRODUCTION		
	Route(s) of Administration	INTRODUCTION		
G.3	REVIEW SUMMARY (For BGTD use only)	---		[Separate *Quality Review Covering Report* (For BGTD use only)]
Part 2 of 4:				
S.	DRUG SUBSTANCE	2.3.S	3.2.S	DRUG SUBSTANCE
S.1	NOMENCLATURE AND CHARACTERIZATION		3.2.S.1 & 3.2.S.3	General Information & Characterisation
S.1.1	Nomenclature	2.3.S.1	*3.2.S.1.1*	*Nomenclature*

***QIS-B-rDNA/ MAbs*; *QIS-B-BLD*; *QIS-B-Conventional Biotherapeutic Products*; and *QIS-B-VAC* in Current Canadian Format**		**Module 2.3 *QOS (Biotech); QOS (Blood Products); QOS (Conventional Biotherapeutic);* and *QOS (Vaccines)* in CTD Format**	**Module 3.2 Body of Data in CTD Format (cross-references to other related subsections)**	
Section#	**Section Name**	**Module#**	**Module#**	**Module Name**
S.1.2	Structure	2.3.S.1 & 2.3.S.3	*3.2.S.1.2* & *3.2.S.3.1*	*Structure* & *Elucidation of Structure and other Characteristics*
S.1.3	Characteristics	2.3.S.1 & 2.3.S.3	*3.2.S.1.3* & *3.2.S.3.1*	*General Properties* & *Elucidation of Structure and other Characteristics*
S.1.4	Elucidation of Structure	2.3.S.1 & 2.3.S.3	*3.2.S.1.2* & *3.2.S.3.1*	*Structure* & *Elucidation of Structure and other Characteristics*
S.2	MANUFACTURE	2.3.S.2	3.2.S.2	Manufacture
*** See the appropriate Appendix for the Location of Information under S.2: Appendix A-1: Specific Drug Substance Section/ Module for Biotechnological/ Biological (Biotech) Products; Appendix A-2: Specific Drug Substance Section/ Module for Blood Products; Appendix A-3: Specific Drug Substance Section/ Module for Conventional Biotherapeutic Products; and Appendix A-4: Specific Drug Substance Section/ Module for Vaccines.				
S.3	CONTROL TESTS ON THE DRUG SUBSTANCE	2.3.S.4	3.2.S.4	Control of Drug Substance
S.3.1	Specifications	2.3.S.4	*3.2.S.4.1*	*Specification*
S.3.2	Analytical Procedures	2.3.S.4	*3.2.S.4.2*	*Analytical Procedures (3.2.S.4.3, 3.2.S.4.5)*
S.3.3	Validation	2.3.S.4	*3.2.S.4.3*	*Validation of Analytical Procedures (3.2.S.4.2, 3.2.S.4.5)*
S.3.4	Impurities	2.3.S.3	*3.2.S.3.2*	*Impurities*
S.3.5	Batch Analyses	2.3.S.4	*3.2.S.4.4*	*Batch Analyses (3.2.S.2.2, 3.2.S.4.2)*
S.3.6	Justification	2.3.S.4	*3.2.S.4.5*	*Justification of Specification (3.2.S.4.2, 3.2.S.4.3)*

***QIS-B-rDNA/ MAbs*; *QIS-B-BLD*; *QIS-B-Conventional Biotherapeutic Products*; and *QIS-B-VAC* in Current Canadian Format**		**Module 2.3 *QOS (Biotech); QOS (Blood Products); QOS (Conventional Biotherapeutic);* and *QOS (Vaccines)* in CTD Format**	**Module 3.2 Body of Data in CTD Format (cross-references to other related subsections)**	
Section#	**Section Name**	**Module#**	**Module#**	**Module Name**
S.4	REFERENCE STANDARD	2.3.S.5 & 2.3.P.6	3.2.S.5 & 3.2.P.6	Reference Standards or Materials & Reference Standards or Materials
S.5	CONTAINER/ CLOSURE	2.3.S.6	3.2.S.6	Container Closure System
S.6	STABILITY	2.3.S.7	3.2.S.7	Stability
S.6.1	Stability Data	2.3.S.7	*3.2.S.7.3*	*Stability Data*
S.6.2	Stability Conclusions	2.3.S.7	*3.2.S.7.1*	*Stability Summary and Conclusions*
S.6.3	Stability Commitment	2.3.S.7	*3.2.S.7.2*	*Post-approval Stability Protocol and Stability Commitment*
Part 3 of 4:				
P.	DRUG PRODUCT	2.3.P	3.2.P	DRUG PRODUCT
P.1	COMPOSITION			
P.1.1	Composition	2.3.P.1	3.2.P.1	Description and Composition of the Drug Product
P.1.1 (a)	Name of all ingredients/components used...	2.3.P.1	3.2.P.1	Description and Composition of the Drug Product
P.1.1 (b)	Confirmation that none of the non-medicinal ingredients (excipients) which appear in the final product are prohibited for use by the Canadian Food and Drugs Act and Regulations	2.3.P.2	*3.2.P.2.1.2*	*Excipients*

***QIS-B-rDNA/ MAbs*; *QIS-B-BLD*; *QIS-B-Conventional Biotherapeutic Products*; and *QIS-B-VAC* in Current Canadian Format**		**Module 2.3 *QOS (Biotech); QOS (Blood Products); QOS (Conventional Biotherapeutic);* and *QOS (Vaccines)* in CTD Format**	**Module 3.2 Body of Data in CTD Format (cross-references to other related subsections)**	
Section#	**Section Name**	**Module#**	**Module#**	**Module Name**
P.1.1 (c)	Information on novel or biological ingredients/excipients	2.3.P.4	*3.2.P.4.5* & *3.2.P.4.6*	*Excipients of Human or Animal Origin (3.2.A.2, 3.2.A.3)* & *Excipients (3.2.A.3)*
P.1.1 (d)	Role of each non-medicinal ingredient/component and biological excipient	2.3.P.2	*3.2.P.2.1.2*	*Excipients*
P.1.2	Investigational Formula(e)	2.3.P.2	*3.2.P.2.2.1*	*Formulation Development*
P.2	DEVELOPMENT PHARMACEUTICS	2.3.P.2	3.2.P.2	Pharmaceutical Development
P.2 (a)	Rationale for choice of dosage form, formulation, and process (including packaging..)	2.3.P.2	*3.2.P.2.1.1* & *3.2.P.2.2.1* & *3.2.P.2.2.3* & *3.2.P.2.3* & *3.2.P.2.4* & *3.2.P.2.5* & *3.2.P.2.6*	*Drug Substance* & *Formulation Development* & *Physicochemical and Biological Properties* & *Manufacturing Process Development* & *Container Closure System* & *Microbiological Attributes* & *Compatibility*
P.2 (b)	Justification of any overages (in composition) used for production	2.3.P.2	*3.2.P.2.2.2*	*Overages*
P.2 (c)	Description of any differences between the drug product used in vitro and in vivo development or stability studies...	2.3.P.2	*3.2.P.2.2.1*	*Formulation Development*
P.2 (d)	Information on batches used in *in-vitro* and *in-vivo* studies	2.3.P.2	*3.2.P.2.2.1*	*Formulation Development*
P.3	MANUFACTURING	2.3.P.3	3.2.P.3	Manufacture
P.3.1	Manufacturer(s)	2.3.P.3	*3.2.P.3.1*	*Manufacturer(s)*

***QIS-B-rDNA/ MAbs*; *QIS-B-BLD*; *QIS-B-Conventional Biotherapeutic Products*; and *QIS-B-VAC* in Current Canadian Format**		**Module 2.3 *QOS (Biotech); QOS (Blood Products); QOS (Conventional Biotherapeutic);* and *QOS (Vaccines)* in CTD Format**	**Module 3.2 Body of Data in CTD Format (cross-references to other related subsections)**	
Section#	**Section Name**	**Module#**	**Module#**	**Module Name**
P.3.2	Manufacturing Formulae	2.3.P.3	*3.2.P.3.2*	*Batch Formula*
P.3.3	Manufacturing Process	2.3.P.3	*3.2.P.3.3*	*Description of Manufacturing Process and Process Controls (3.2.P.3.3-3.2.P.3.5, 3.2.A.1)*
P.3.3 (e)	Blank manufacturing documents	—		No longer required as part of the drug submission.
P.3.4	In-Process Controls	2.3.P.3	*3.2.P.3.3*	*Description of Manufacturing Process and Process Controls (3.2.P.3.4)*
P.3.5	Control of Intermediates	2.3.P.3	*3.2.P.3.4*	*Controls of Critical Steps and Intermediates (3.2.P.3.3, 3.2.P.4.2, 3.2.P.4.3, 3.2.P.5.2, 3.2.P.5.3)*
P.3.6	Validation of the Process	2.3.P.3	*3.2.P.3.5*	*Process Validation and/or Evaluation (3.2.P.3.3, 3.2.A.2)*
P.4	CONTROL TESTS ON EXCIPIENTS	2.3.P.4	3.2.P.4	Control of Excipients
P.4.1	Specifications	2.3.P.4	*3.2.P.4.1*	*Specifications (3.2.A.3)*
P.4.2	Analytical Procedures	---	*3.2.P.4.2*	*Analytical Procedures*
P.4.3	Validation	---	*3.2.P.4.3*	*Validation of Analytical Procedures*
P.4.4	Justification	2.3.P.4	*3.2.P.4.4*	*Justification of Specifications*
P.5	CONTROL TESTS ON THE DRUG PRODUCT	2.3.P.5	3.2.P.5	Control of Drug Product
P.5.1	Specification	2.3.P.5	*3.2.P.5.1*	*Specification(s)*
P.5.2	Analytical Procedures	2.3.P.5	*3.2.P.5.2*	*Analytical Procedures (3.2.P.5.3, 3.2.P.5.5, 3.2.P.5.6)*

***QIS-B-rDNA/ MAbs*; *QIS-B-BLD*; *QIS-B-Conventional Biotherapeutic Products*; and *QIS-B-VAC* in Current Canadian Format**		**Module 2.3 *QOS (Biotech); QOS (Blood Products); QOS (Conventional Biotherapeutic);* and *QOS (Vaccines)* in CTD Format**	**Module 3.2 Body of Data in CTD Format (cross-references to other related subsections)**	
Section#	**Section Name**	**Module#**	**Module#**	**Module Name**
P.5.3	Validation	2.3.P.5	*3.2.P.5.3*	*Validation of Analytical Procedures (3.2.P.5.2, 3.2.P.5.5, 3.2.P.5.6)*
P.5.4	Degradation Products	2.3.P.5	*3.2.P.5.5*	*Characterisation of Impurities (3.2.S.3.2, 3.2.P.5.2, 3.2.P.5.3, 3.2.P.5.6)*
P.5.5	Batch Analysis	2.3.P.5	*3.2.P.5.4*	*Batch Analyses (3.2.P.2.2, 3.2.P.5.2)*
P.5.5 (h)	Lot Release documentation	---	3.2.R.3	Lot Release Documentation (for Canada)
P.5.6	Justification of Specifications	2.3.P.5	*3.2.P.5.6*	*Justification of Specification(s) (3.2.P.5.2, 3.2.P.5.3, 3.2.P.5.5)*
P.6	CONTAINER/ CLOSURE	2.3.P.7	3.2.P.7	Container Closure System
P.6.1	Description	2.3.P.7	3.2.P.7	Container Closure System
P.6.2	Composition	2.3.P.7	3.2.P.7	Container Closure System
P.6.3	Specification	2.3.P.7	3.2.P.7	Container Closure System
P.6.4	Analytical Procedures	2.3.P.7	3.2.P.7	Container Closure System
P.6.5	Validation	2.3.P.7	3.2.P.7	Container Closure System
P.6.6	Qualification of Container/Closure System	2.3.P.7	3.2.P.7	Container Closure System *(3.2.P.2.4)*
P.7	STABILITY	2.3.P.8	3.2.P.8	Stability
S.7.1	Stability Data	2.3.P.8	*3.2.P.8.3*	*Stability Data*
S.7.2	Stability Conclusions	2.3.P.8	*3.2.P.8.1*	*Stability Summary and Conclusion*
S.7.3	Production Stability Protocol	2.3.P.8	*3.2.P.8.2*	*Post-approval Stability Protocol and Stability Commitment*

***QIS-B-rDNA/ MAbs*; *QIS-B-BLD*; *QIS-B-Conventional Biotherapeutic Products*; and *QIS-B-VAC* in Current Canadian Format**		**Module 2.3 *QOS (Biotech); QOS (Blood Products); QOS (Conventional Biotherapeutic);* and *QOS (Vaccines)* in CTD Format**	**Module 3.2 Body of Data in CTD Format (cross-references to other related subsections)**	
Section#	**Section Name**	**Module#**	**Module#**	**Module Name**
Part 4 of 4:				
O.	OTHER INFORMATION			
O.1	ESTABLISHMENT-RELATED INFORMATION	2.3.A.1	3.2.A.1 & 1.2.5	Facilities and Equipment & GMP and Establishment Licensing Information
O.1 (a)	Establishment licensing and GMP compliance information for each establishment involved in the manufacture of the bulk process intermediate, drug substance, drug product or dosage form	---	1.2.5	GMP and Establishment Licensing Information
O.1 (b)	Plant Process Flow and Interaction	2.3.A.1	3.2.A.1	Facilities and Equipment
O.2	PACKAGE INFORMATION		1.3	Product Labelling
O.2.1	Availability and How Supplied	---	1.3.1	Product Monograph
O.2.2 O.2.2 (a) & O.2.2 (b)	Reconstitution Diluent(s) Information on the diluent & Information on the container/closure of diluent	2.3.P.1	3.2.P.1	Description and Composition of the Drug Product AND/OR a separate 3.2.P DRUG PRODUCT section for a reconstitution diluent without a DIN
O.2.3	Medical Device(s)	---	3.2.R.2	Medical Devices (for Canada)
O.2.4	Package Insert	---	1.3.2 & 1.3.3	Inner & Outer Labels & Non-Canadian Package Inserts
O.2.5	Labels	---	1.3.2	Inner & Outer Labels

***QIS-B-rDNA/ MAbs*; *QIS-B-BLD*; *QIS-B-Conventional Biotherapeutic Products*; and *QIS-B-VAC* in Current Canadian Format**		**Module 2.3 *QOS (Biotech); QOS (Blood Products); QOS (Conventional Biotherapeutic);* and *QOS (Vaccines)* in CTD Format**	**Module 3.2 Body of Data in CTD Format (cross-references to other related subsections)**	
Section#	**Section Name**	**Module#**	**Module#**	**Module Name**
O.3	PRODUCT MONOGRAPH (For New Drugs ONLY)			
O.3 (a)	Electronic copy of draft PM	—	1.6	Electronic Review Documents
O.3 (b)	Hardcopy of draft PM	---	1.3.1	Product Monograph
O.4	CERTIFIED PRODUCT INFORMATION DOCUMENT			
O.4 (a)	Electronic copy of *CPID-B*	—	1.6	Electronic Review Documents
O.4 (b)	Hardcopy of *CPID-B*	---	1.4.1	Certified Product Information Document (for Canada)
O.5	REFERENCES	—	3.3	LITERATURE REFERENCES
O.6	APPENDICES	—		(See *ICH CTD-Q Q&A/ Location Issues* document on how to handle attachments.)

Appendix A-1: Location of Quality Information in the Current Canadian Versus CTD Formats: Specific Drug Substance Section/ Module for Biotechnological/ Biological (Biotech) Products

***QIS-B-rDNA/ MAbs* in Current Canadian Format**		**Module 2.3 *QOS (Biotech)* in CTD Format**	**Module 3.2 Body of Data in CTD Format (cross-references to other related subsections)**	
Section#	**Section Name**	**Module#**	**Module#**	**Module Name**
Part 2 of 4:				
S.2	MANUFACTURE	2.3.S.2	3.2.S.2	Manufacture
S.2.1	Manufacturer(s)	2.3.S.2	*3.2.S.2.1*	*Manufacturer(s)*
S.2.2	Description of Synthesis/ Manufacture	2.3.S.2	*3.2.S.2.2*	*Description of Manufacturing Process and Process Controls (3.2.S.2.3-3.2.S.2.5, 3.2.A.1)*
S.2.3	In-Process Controls	2.3.S.2	*3.2.S.2.2*	*Description of Manufacturing Process and Process Controls (3.2.S.2.4)*
S.2.4	Raw Materials	2.3.S.2	*3.2.S.2.3*	*Control of Materials*
S.2.4 (a)	Biological starting materials	2.3.S.2	*3.2.S.2.3*	*Control of Source and Starting Materials of Biological Origin (3.2.A.2)*
S.2.4 (a) (I)	Molecular biology of the gene and expression construct...	2.3.S.2	*3.2.S.2.3*	*Source, history, and generation of the cell substrate*
S.2.4 (a) (ii)	Generation and Characterization of Cell Banks, Seed Banks, or Cell Substrates	2.3.S.2	*3.2.S.2.3*	*Cell banking system, characterisation, and testing*
S.2.4 (a) (iii)	Qualification of Cell Banks, Seed Banks, or Cell Substrates	2.3.S.2	*3.2.S.2.3*	*Cell banking system, characterisation, and testing*
S.2.4 (a) (iv)	Storage and Maintenance	2.3.S.2	*3.2.S.2.3*	*Cell banking system, characterisation, and testing*
S.2.4 (b)	Other Raw Materials			
S.2.4 (b) (I)	Nonmedicinal Ingredients	---	*3.2.S.2.3*	*Control of Materials*
S.2.4 (b) (ii)	Biological auxiliary materials and/or biological excipients	2.3.S.2	*3.2.S.2.3*	*Control of Source and Starting Materials of Biological Origin (3.2.A.2, 3.2.A.3)*

***QIS-B-rDNA/ MAbs* in Current Canadian Format**		**Module 2.3 *QOS (Biotech)* in CTD Format**	**Module 3.2 Body of Data in CTD Format (cross-references to other related subsections)**	
Section#	**Section Name**	**Module#**	**Module#**	**Module Name**
S.2.4 (b) (iii)	Prepared Reagents	---	*3.2.S.2.3*	*Control of Materials*
S.2.5	Quality Control of Isolated Intermediates	2.3.S.2	*3.2.S.2.4*	*Controls of Critical Steps and Intermediates (3.2.S.2.2, 3.2.S.4.2, 3.2.S.4.3)*
S.2.6	Process Validation			
S.2.6 (a)	Manufacturing process validation			
S.2.6 (a) (I)	Summary of validation studies for current manufacturing process	2.3.S.2	*3.2.S.2.5*	*Process Validation and/or Evaluation (3.2.S.2.2, 3.2.S.2.4, 3.2.S.4.3, 3.2.A.2)*
S.2.6 (a) (ii)	Summary of validation studies related to changes in production	2.3.S.2	*3.2.S.2.6*	*Manufacturing Process Development (3.2.S.2.2, 3.2.S.2.5, 3.2.S.3.2, 3.2.S.4.4)*
S.2.6 (b)	Viral safety validation	2.3.A.2	3.2.A.2	Adventitious Agents Safety Evaluation Viral Clearance Studies *(3.2.S.2.5, 3.2.P.3.5)*

Appendix A-2: Location of Quality Information in the Current Canadian Versus CTD Formats: Specific Drug Substance Section/ Module for Blood Products

***QIS-B-BLD* in Current Canadian Format**		**Module 2.3 *QOS (Blood Products)* in CTD Format**	**Module 3.2 Body of Data in CTD Format (cross-references to other related subsections)**	
Section#	**Section Name**	**Module#**	**Module#**	**Module Name**
Part 2 of 4:				
S.2	MANUFACTURE	2.3.S.2	3.2.S.2	Manufacture
S.2.1	Manufacturer(s)	2.3.S.2	*3.2.S.2.1*	*Manufacturer(s)*
S.2.2	Description of Synthesis/ Manufacture	2.3.S.2	*3.2.S.2.2*	*Description of Manufacturing Process and Process Controls (3.2.S.2.3-3.2.S.2.5, 3.2.A.1)*
S.2.3	In-Process Controls	2.3.S.2	*3.2.S.2.2*	*Description of Manufacturing Process and Process Controls (3.2.S.2.4)*
S.2.4	Raw Materials	2.3.S.2	*3.2.S.2.3*	*Control of Materials*
S.2.4 (a)	Biological starting materials	2.3.S.2	*3.2.S.2.3*	*Control of Source and Starting Materials of Biological Origin (3.2.A.2)*
S.2.4 (a) (I)	Plasma Source(s)	2.3.S.2	*3.2.S.2.3*	*Origin and Collection of the Source and Starting Material*
S.2.4 (a) (ii)	Blood Collection Centres	2.3.S.2	*3.2.S.2.3*	*Origin and Collection of the Source and Starting Material*
S.2.4 (a) (iii)	Donor Selection/ Deferral Requirements	2.3.S.2	*3.2.S.2.3*	*Donor Suitability, Testing, and Screening*
S.2.4 (a) (iv)	Plasma Unit Screening	2.3.S.2	*3.2.S.2.3*	*Donor Suitability, Testing, and Screening*
S.2.4 (a) (v)	Hold Times	2.3.S.2	*3.2.S.2.3*	*Origin and Collection of the Source and Starting Material*
S.2.4 (a) (vi)	Trace backs/ Look back	2.3.S.2	*3.2.S.2.3*	*Additional Safety Measures on the Source and/or Starting Material*
S.2.4 (b)	Other Raw Materials			
S.2.4 (b) (I)	Nonmedicinal Ingredients	---	*3.2.S.2.3*	*Control of Materials*

***QIS-B-BLD* in Current Canadian Format**		**Module 2.3 *QOS (Blood Products)* in CTD Format**	**Module 3.2 Body of Data in CTD Format (cross-references to other related subsections)**	
Section#	**Section Name**	**Module#**	**Module#**	**Module Name**
S.2.4 (b) (ii)	Biological auxiliary materials and/or biological excipients	2.3.S.2	*3.2.S.2.3*	*Control of Source and Starting Materials of Biological Origin (3.2.A.2, 3.2.A.3)*
S.2.4 (b) (iii)	Prepared Reagents	---	*3.2.S.2.3*	*Control of Materials*
S.2.5	Quality Control of Isolated Intermediates	2.3.S.2	*3.2.S.2.4*	*Controls of Critical Steps and Intermediates (3.2.S.2.2, 3.2.S.4.2, 3.2.S.4.3)*
S.2.5 (a) (I)	Plasma Pool Size	2.3.S.2	*3.2.S.2.4*	*Controls of Critical Steps and Intermediates: Intermediates*
S.2.5 (a) (ii)	Plasma Pool Screening	2.3.S.2	*3.2.S.2.4*	*Controls of Critical Steps and Intermediates: Intermediates*
S.2.5 (b)	Testing of other isolated, pivotal, key, and critical intermediates	2.3.S.2	*3.2.S.2.4*	*Controls of Critical Steps and Intermediates: Critical Steps*
S.2.6	Process Validation			
S.2.6 (a)	Manufacturing process validation			
S.2.6 (a) (I)	Summary of validation studies for current manufacturing process	2.3.S.2	*3.2.S.2.5*	*Process Validation and/or Evaluation (3.2.S.2.2, 3.2.S.2.4, 3.2.S.4.3, 3.2.A.2)*
S.2.6 (a) (ii)	Summary of validation studies related to changes in production	2.3.S.2	*3.2.S.2.6*	*Manufacturing Process Development (3.2.S.2.2, 3.2.S.2.5, 3.2.S.3.2, 3.2.S.4.4)*
S.2.6 (b)	Viral safety validation	2.3.A.2	3.2.A.2	Adventitious Agents Safety Evaluation Viral Clearance Studies *(3.2.S.2.5, 3.2.P.3.5)*

Appendix A-3: Location of Quality Information in the Current Canadian Versus CTD Formats: Specific Drug Substance Section/ Module for Conventional Biotherapeutic Products

***QIS-B-Conventional Biotherapeutic* in Current Canadian Format**		**Module 2.3 *QOS (Conventional Biotherapeutic)* in CTD Format**	**Module 3.2 Body of Data in CTD Format (cross-references to other related subsections)**	
Section#	**Section Name**	**Module#**	**Module#**	**Module Name**
Part 2 of 4:				
S.2	MANUFACTURE	2.3.S.2	3.2.S.2	Manufacture
S.2.1	Manufacturer(s)	2.3.S.2	*3.2.S.2.1*	*Manufacturer(s)*
S.2.2	Description of Synthesis/ Manufacture	2.3.S.2	*3.2.S.2.2*	*Description of Manufacturing Process and Process Controls (3.2.S.2.3-3.2.S.2.5, 3.2.A.1)*
S.2.3	In-Process Controls	2.3.S.2	*3.2.S.2.2*	*Description of Manufacturing Process and Process Controls (3.2.S.2.4)*
S.2.4	Raw Materials	2.3.S.2	*3.2.S.2.3*	*Control of Materials*
S.2.4 (a)	Biological starting materials	2.3.S.2	*3.2.S.2.3*	*Control of Source and Starting Materials of Biological Origin: Control of Starting Material for the Conventional Biotherapeutic (3.2.A.2)*
S.2.4 (b)	Other Raw Materials			
S.2.4 (b) (I)	Nonmedicinal Ingredients	---	*3.2.S.2.3*	*Control of Materials*
S.2.4 (b) (ii)	Biological auxiliary materials and/or biological excipients	2.3.S.2	*3.2.S.2.3*	*Control of Source and Starting Materials of Biological Origin (3.2.A.2, 3.2.A.3)*
S.2.4 (b) (iii)	Prepared Reagents	---	*3.2.S.2.3*	*Control of Materials*
S.2.5	Quality Control of Isolated Intermediates	2.3.S.2	*3.2.S.2.4*	*Controls of Critical Steps and Intermediates (3.2.S.2.2, 3.2.S.4.2, 3.2.S.4.3)*
S.2.6	Process Validation			
S.2.6 (a)	Manufacturing process validation			

***QIS-B-Conventional Biotherapeutic* in Current Canadian Format**		**Module 2.3 *QOS (Conventional Biotherapeutic)* in CTD Format**	**Module 3.2 Body of Data in CTD Format (cross-references to other related subsections)**	
Section#	**Section Name**	**Module#**	**Module#**	**Module Name**
S.2.6 (a) (I)	Summary of validation studies for current manufacturing process	2.3.S.2	*3.2.S.2.5*	*Process Validation and/or Evaluation (3.2.S.2.2, 3.2.S.2.4, 3.2.S.4.3, 3.2.A.2)*
S.2.6 (a) (ii)	Summary of validation studies related to changes in production	2.3.S.2	*3.2.S.2.6*	*Manufacturing Process Development (3.2.S.2.2, 3.2.S.2.5, 3.2.S.3.2, 3.2.S.4.4)*
S.2.6 (b)	Viral safety validation	2.3.A.2	3.2.A.2	Adventitious Agents Safety Evaluation Viral Clearance Studies *(3.2.S.2.5, 3.2.P.3.5)*

Appendix A-4: Location of Quality Information in the Current Canadian Versus CTD Formats: Specific Drug Substance Section/ Module for Vaccines

***QIS-B-VAC* in Current Canadian Format**		**Module 2.3 *QOS (Vaccines)* in CTD Format**	**Module 3.2 Body of Data in CTD Format (cross-references to other related subsections)**	
Section#	**Section Name**	**Module#**	**Module#**	**Module Name**
Part 2 of 4:				
S.2	MANUFACTURE	2.3.S.2	3.2.S.2	Manufacture
S.2.1	Manufacturer(s)	2.3.S.2	*3.2.S.2.1*	*Manufacturer(s)*
S.2.2	Description of Synthesis/ Manufacture	2.3.S.2	*3.2.S.2.2*	*Description of Manufacturing Process and Process Controls (3.2.S.2.3-3.2.S.2.5, 3.2.A.1)*
S.2.3	In-Process Controls	2.3.S.2	*3.2.S.2.2*	*Description of Manufacturing Process and Process Controls (3.2.S.2.4)*
S.2.4	Raw Materials	2.3.S.2	*3.2.S.2.3*	*Control of Materials*
S.2.4 (a)	Biological starting materials	2.3.S.2	*3.2.S.2.3*	*Control of Source and Starting Materials of Biological Origin (3.2.A.2)*
S.2.4 (a) (I)	History of pre-master seed	2.3.S.2	*3.2.S.2.3*	*Source, history, and generation of the cell/ seed substrate*
S.2.4 (a) (ii)	Molecular biology of the gene and expression construct		*3.2.S.2.3*	*Source, history, and generation of the cell/ seed substrate* (Not applicable to a conventional vaccine)
S.2.4 (a) (iii)	Generation and Characterization of Cell Banks, Seed Banks, or Cell Substrates	2.3.S.2	*3.2.S.2.3*	*Cell/ seed banking system, characterisation, and testing*
S.2.4 (a) (iv)	Qualification of Cell Banks, Seed Banks, or Cell Substrates	2.3.S.2	*3.2.S.2.3*	*Cell/ seed banking system, characterisation, and testing*
S.2.4 (a) (v)	Storage and Maintenance	2.3.S.2	*3.2.S.2.3*	*Cell/ seed banking system, characterisation, and testing*
S.2.4 (b)	Other Raw Materials			
S.2.4 (b) (I)	Nonmedicinal Ingredients	---	*3.2.S.2.3*	*Control of Materials*

QIS-B-VAC **in Current Canadian Format**		**Module 2.3 *QOS* *(Vaccines)* in CTD Format**	**Module 3.2 Body of Data in CTD Format (cross-references to other related subsections)**	
Section#	**Section Name**	**Module#**	**Module#**	**Module Name**
S.2.4 (b) (ii)	Biological auxiliary materials and/or biological excipients	2.3.S.2	*3.2.S.2.3*	*Control of Source and Starting Materials of Biological Origin (3.2.A.2, 3.2.A.3*)
S.2.4 (b) (iii)	Prepared Reagents	---	*3.2.S.2.3*	*Control of Materials*
S.2.4 (b) (iv)	Adjuvants	2.3.S.2	*3.2.S.2.3*	*Control of Materials*
S.2.5	Quality Control of Isolated Intermediates	2.3.S.2	*3.2.S.2.4*	*Controls of Critical Steps and Intermediates (3.2.S.2.2, 3.2.S.4.2, 3.2.S.4.3)*
S.2.6	Process Validation			
S.2.6 (a)	Manufacturing process validation			
S.2.6 (a) (I)	Summary of validation studies for current manufacturing process	2.3.S.2	*3.2.S.2.5*	*Process Validation and/or Evaluation (3.2.S.2.2, 3.2.S.2.4, 3.2.S.4.3, 3.2.A.2)*
S.2.6 (a) (ii)	Summary of validation studies related to changes in production	2.3.S.2	*3.2.S.2.6*	*Manufacturing Process Development (3.2.S.2.2, 3.2.S.2.5, 3.2.S.3.2, 3.2.S.4.4)*
S.2.6 (b)	Viral safety validation	2.3.A.2	3.2.A.2	Adventitious Agents Safety Evaluation Viral Clearance Studies *(3.2.S.2.5, 3.2.P.3.5)*

Appendix B: Location of Quality Information in the Current Canadian Versus CTD Formats: Radiopharmaceutical (Schedule C) Products

***QIS-R* in Current Canadian Format**		**Module 2.3 *QOS* *(Radiopharm)* in CTD Format**	**Module 3.2 Body of Data in CTD Format (cross-references to other related subsections)**	
Section#	**Section Name**	**Module#**	**Module#**	**Module Name**
G.	GENERAL INFORMATION			
G.1	SUBMISSION SUMMARY	INTRODUCTION		
	Brand Name	INTRODUCTION		
	Proper or Common Name	INTRODUCTION		
	Code Name or Number			
	Submission Sponsor	INTRODUCTION		
	Drug Classification	INTRODUCTION		
G.2	DRUG SUMMARY			
	Therapeutic Classification	INTRODUCTION		
	Code Name or Number	INTRODUCTION		
	Dosage Form(s)	INTRODUCTION		
	Strength(s)	INTRODUCTION		
	Route(s) of Administration	INTRODUCTION		
G.3	REVIEW SUMMARY (For BGTD use only)	---		[Separate *Quality Review Covering Report* (For BGTD use only)]
S.	DRUG SUBSTANCE	2.3.S	3.2.S	DRUG SUBSTANCE
S.1	NOMENCLATURE AND CHARACTERIZATION		3.2.S.1 & 3.2.S.3	General Information & Characterisation
S.1.1	Nomenclature	2.3.S.1	*3.2.S.1.1*	*Nomenclature*
S.1.2	Structure	2.3.S.1 & 2.3.S.3	*3.2.S.1.2* & *3.2.S.3.1*	*Structure* & *Elucidation of Structure and other Characteristics*
S.1.3	Physicochemical Characteristics	2.3.S.1 & 2.3.S.3	*3.2.S.1.3* & *3.2.S.3.1*	*General Properties* & *Elucidation of Structure and other Characteristics*

***QIS-R* in Current Canadian Format**		**Module 2.3 *QOS (Radiopharm)* in CTD Format**	**Module 3.2 Body of Data in CTD Format (cross-references to other related subsections)**	
Section#	**Section Name**	**Module#**	**Module#**	**Module Name**
S.1.4	Radionuclidic and Radiochemical properties	2.3.S.1 & 2.3.S.3	3.2.S.3.1	*Elucidation of Structure and other Characteristics*
S.1.5	Elucidation of Chemical Structure	2.3.S.1 & 2.3.S.3	*3.2.S.1.2 &* *3.2.S.3.1*	*Structure &* *Elucidation of Structure and other Characteristics*
S.2	FABRICATION	2.3.S.2	3.2.S.2	*Manufacture*
S.2.1	Fabricator(s)	2.3.S.2	*3.2.S.2.1*	*Manufacturer(s)*
S.2.2	Quality Control of Starting Materials	2.3.S.2	3.2.S2.3	*Control of Materials*
S.2.3	Description of Synthesis/ Fabrication	2.3.S.2	*3.2.S.2.2*	*Description of Manufacturing Process and Process Controls (3.2.S.2.3-3.2.S.2.5, 3.2.A.1)*
S.2.4	In-Process Controls	2.3.S.2	*3.2.S.2.2*	*Description of Manufacturing Process and Process Controls (3.2.S.2.4)*
S.3	CONTROL TESTS ON THE DRUG SUBSTANCE	2.3.S.4	3.2.S.4	Control of Drug Substance
S.3.1	Specifications	2.3.S.4	*3.2.S.4.1*	*Specification*
S.3.2	Justification of Specifications	2.3.S.4	*3.2.S.4.5*	*Justification of Specification (3.2.S.4.2, 3.2.S.4.3)*
S.3.3	Test Methods Validation	2.3.S.4	*3.2.S.4.3*	*Validation of Analytical Procedures*
S.3.4	Impurities and Their Qualification	2.3.S.3	*3.2.S.3.2*	*Impurities*
S.3.5	Reference Standard	2.3.S.5	3.2.S.5	*Reference Standards or Materials*
S.3.6	Batch Analyses	2.3.S.4	*3.2.S.4.4*	*Batch Analyses (3.2.S.2.2, 3.2.S.4.2)*
S.4	CONTAINER/ CLOSURE	2.3.S.6	3.2.S.6	Container Closure System
S.5	STABILITY	2.3.S.7	3.2.S.7	Stability
S.5.1	Stability Data	2.3.S.7	*3.2.S.7.3*	*Stability Data*

***QIS-R* in Current Canadian Format**		**Module 2.3 *QOS* *(Radiopharm)* in CTD Format**	**Module 3.2 Body of Data in CTD Format (cross-references to other related subsections)**	
Section#	**Section Name**	**Module#**	**Module#**	**Module Name**
S.5.2	Stability Conclusions	2.3.S.7	*3.2.S.7.1*	*Stability Summary and Conclusions*
		2.3.S.7	*3.2.S.7.2*	*Post-approval Stability Protocol and Stability Commitment*
P.	DRUG PRODUCT	2.3.P	3.2.P	DRUG PRODUCT
P.1	Development Pharmaceutics	2.3.P.2	3.2.P.2	*Pharmaceutical Development*
P.2	FABRICATION	2.3.P.3	3.2P.3	*Manufacture*
P.2.1	Activities	2.3.P.3 & ---	*3.2.P.3.1* & 1.2.5	*Manufacturer(s)* & GMP and Establishment Licensing Information
P.2.2	Formulation	2.3.P.3	*3.2.P.3.2*	*Batch Formula*
P.2.3	Fabrication Process	2.3.P.3	*3.2.P.3.3*	*Description of Manufacturing Process and Process Controls (3.2.P.3.3-3.2.P.3.5, 3.2.A.1)*
P.2.4	In-Process Controls	2.3.P.3	*3.2.P.3.3*	*Description of Manufacturing Process and Process Controls (3.2.P.3.4)*
		2.3.P.3	*3.2.P.3.4*	*Controls of Critical Steps and Intermediates (3.2.P.3.3, 3.2.P.4.2, 3.2.P.4.3, 3.2.P.5.2, 3.2.P.5.3)*
P.2.5	Validation of the Process	2.3.P.3	*3.2.P.3.5*	*Process Validation and/or Evaluation (3.2.P.3.3, 3.2.A.2)*
P.3	CONTROL TESTS ON ALL INGREDIENTS (excluding drug substance)	2.3.P.4	3.2.P.4	Control of Excipients
P.3 (b)	Specifications for all ingredients	2.3.P.4	*3.2.P.4.1*	*Specifications (3.2.A.3)*
P.3 (c)	Control tests for all ingredients	---	*3.2.P.4.2*	*Analytical Procedures*
		2.3.P.4	*3.2.P.4.4*	*Justification of Specifications*
P.4	CONTROL TESTS ON THE DRUG PRODUCT	2.3.P.5	3.2.P.5	Control of Drug Product

***QIS-R* in Current Canadian Format**		**Module 2.3 *QOS* *(Radiopharm)* in CTD Format**	**Module 3.2 Body of Data in CTD Format (cross-references to other related subsections)**	
Section#	**Section Name**	**Module#**	**Module#**	**Module Name**
P.4.1	Specification	2.3.P.5	*3.2.P.5.1*	*Specification(s)*
P.4.2	Justification of Specifications	2.3.P.5	*3.2.P.5.6*	*Justification of Specification(s) (3.2.P.5.2, 3.2.P.5.3, 3.2.P.5.5)*
P.4.3	Test methods and Validation	2.3.P.5	*3.2.P.5.2* & *3.2.P.4.3* *& 3.2.P.5.3*	*Analytical Procedures (3.2.P.5.3, 3.2.P.5.5, 3.2.P.5.6)* & *Validation of Analytical Procedures* & *Validation of Analytical Procedures (3.2.P.5.2, 3.2.P.5.5, 3.2.P.5.6)*
		2.3.P.5	*3.2.P.5.5*	*Characterisation of Impurities (3.2.S.3.2, 3.2.P.5.2, 3.2.P.5.3, 3.2.P.5.6)*
P.4.4	Batch Analyses	2.3.P.5	*3.2.P.5.4*	*Batch Analyses (3.2.P.2.2, 3.2.P.5.2)*
		---	3.2.R.3	Lot Release Documentation (for Canada)
P.5	CONTAINER/ CLOSURE	2.3.P.7	3.2.P.7	Container Closure System
P.5.1	Source	2.3.P.7	3.2.P.7	Container Closure System
P.5.2	Description	2.3.P.7	3.2.P.7	Container Closure System
P.5.3	Composition	2.3.P.7	3.2.P.7	Container Closure System
P.5.4	Specifications	2.3.P.7	3.2.P.7	Container Closure System
P.5.5	Qualification of Container/ Closure System	2.3.P.7	3.2.P.7	Container Closure System *(3.2.P.2.4)*
P.6	STABILITY	2.3.P.8	3.2.P.8	Stability
P.6.1	Stability Data	2.3.P.8	*3.2.P.8.3*	*Stability Data*
P.6.2	Stability Conclusions	2.3.P.8	*3.2.P.8.1*	*Stability Summary and Conclusion*
P.6.3	Post Market Stability Protocol	2.3.P.8	*3.2.P.8.2*	*Post-approval Stability Protocol and Stability Commitment*

***QIS-R* in Current Canadian Format**		**Module 2.3 *QOS* *(Radiopharm)* in CTD Format**	**Module 3.2 Body of Data in CTD Format (cross-references to other related subsections)**	
Section#	**Section Name**	**Module#**	**Module#**	**Module Name**
		2.3.P.1	3.2.P.1	Description and Composition of the Drug Product AND/OR a separate 3.2.P DRUG PRODUCT section for a reconstitution diluent without a DIN
O.	OTHER INFORMATION			
O.1(a)	PRODUCT MONOGRAPH/ INVESTIGATORS' BROCHURE	---	1.3.1	Product Monograph
O.1(b)	Electronic copy of the PM/ Investigator's Brochure	—	1.6	Electronic Review Documents
O.1(c)	LABELS	---	1.3 1.3.2	Product Labelling Inner and Outer Labels
		2.3.A.1	3.2.A.1	Facilities and Equipment
		---	3.2.R.2	Medical Devices (for Canada)
	CERTIFIED PRODUCT INFORMATION DOCUMENT-RADIO-PHARMACEUTICALS	---	1.4.1	Certified Product Information Document (for Canada)
O.2	APPENDICES	—		(See *ICH CTD-Q Q&A/ Location Issues* document on how to handle attachments.)
O.3	REFERENCES	—	3.3	LITERATURE REFERENCES