

NOTICE

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Health Canada is pleased to announce the release of the following finalized Quality Summary templates (collectively referred to as *QOS-CE templates*), which are meant to assist applicants in the preparation of drug submissions:

- Quality Overall Summary - Chemical Entities (Clinical Trial Applications - Phase I) (QOS-CE (CTA - Phase I)),
- Quality Overall Summary - Chemical Entities (Clinical Trial Applications - Phase II/III) (QOS-CE (CTA - Phase II/III)),
- Quality Overall Summary - Chemical Entities (Clinical Trial Applications - Bioavailability Studies) (QOS-CE (CTA - BA)),
- Quality Overall Summary - Chemical Entities (New Drug Submissions/Abbreviated New Drug Submissions) (QOS-CE (NDS/ANDS)),
- - Certified Product Information Document - Chemical Entities (CPID-CE),
- Quality Overall Summary - Chemical Entities (Applications for Drug Identification Number Submissions) (QOS-CE (DINA)).

A Quality Overall Summary (QOS) is part of a drug submission organized according to the *International Conference on Harmonization (ICH) Common Technical Document (CTD)* format. The QOS represents a summary that follows the scope and the outline of the Quality Body of Data of the submission. These QOS-CE templates can be used by sponsors to summarize the Quality information for drug submissions containing drug substances and their corresponding products of synthetic or semi-synthetic origin that are filed with Health Canada pursuant to Part C, Division 1, 5, or 8 of the *Food and Drug Regulations*. This would exclude submissions for Biotechnological/Biological (Schedule D) and Radiopharmaceutical (Schedule C) drugs.

A QOS prepared in accordance with **either** the ICH CTD-Q guidance or according to Health Canada's QOS-CE templates would be considered acceptable on filing. The QOS-CE would be considered an acceptable replacement for the Quality Overall Summary defined by the CTD-Q guidance as its use promotes review efficiencies by serving as the basis for the Quality assessment report and provides additional guidance with respect to technical content requirements.

These finalized templates replace previous versions of the templates that were available in either draft (e.g., CTAs, DINAs) or in final (e.g., NDSs, ANDSs, CPID-CE) form. The QOS-CE templates have been updated to:

- be consistent with developments with ICH's CTD (e.g., notably the release of the Step 4 CTD-*Quality Questions and Answers / Location Issues* document),
- reflect revisions as a result of comments received during the Stakeholder consultation period, where appropriate,
- streamline their structure (e.g., reduce the number of heavily formatted tables),
- address concerns over proprietary software specifications. **These templates are now available in both Corel® WordPerfect and Microsoft® Word to assist sponsors in their use. Please note:** Sponsors are requested to submit original data files only in Microsoft Word 2000 and above or in Corel WordPerfect versions 6, 7, 8, 9, or 10. Sponsors must use the appropriate template for the original word processing format of their choice (i.e., Word template for Word submissions and WordPerfect template for WordPerfect submissions).

Certified Product Information Document - Chemical Entities (CPID-CE):

As the CPID-CE has an important role in the overall process (e.g., assessments of post-approval changes, Inspections, Provincial Formulary processes) its use will continue. A CPID-CE should continue to be included with NDSs and ANDSs (and subsequent changes) regardless of the format used for the Quality Overall Summary included in an NDS or ANDS (e.g., according to ICH's CTD guidance or Health Canada's QOS-CE (NDS) template).

Other Related Quality Guidance Documents:

Health Canada is in the process of finalizing the Quality guidance documents for "pharmaceuticals" (chemical entities) for: CTAs, NDSs and ANDSs, and DINAs. Draft versions of these documents are available on the Therapeutic Products Directorate's (TPD) Website and can be consulted for additional information. In addition, a *Sample Completed QOS-CE* is currently under development which would provide additional guidance in terms of completing the Quality Overall Summary.

Should you have any questions or comments regarding the content of these QOS-CE templates, please contact:

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