Quality Systems for Regulatory Review at Health Canada

November 7, 2012

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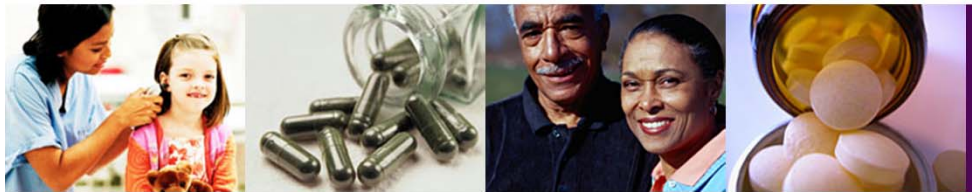
Canada

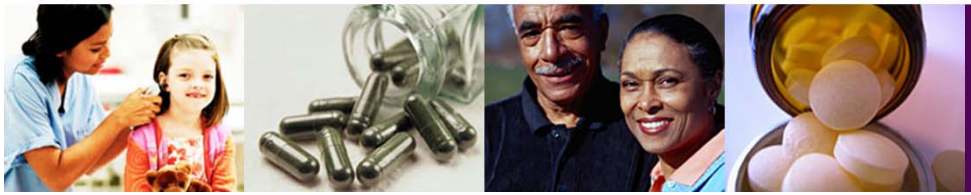
Health Canada GRP Project

- The Therapeutic Products Directorate Good Review Practices project (for human medical devices and pharmaceuticals) was launched in 2004
- It is not (yet) a formal Quality System
- The development of Standard Operating Procedures (SOPs) is a large part of the GRP Project



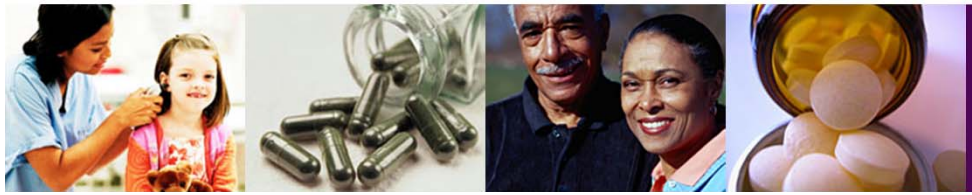
Scope of Review SOPs

- SOPs provide instructions for reviewers on how to prepare regulatory review reports for medical device and drug applications (*Say What You Do*)
- Different SOPs apply to different
  - stages of development (e.g. investigational testing versus marketing authorisation),
  - application types (e.g. generic versus innovative drugs),
  - types of review (e.g. clinical versus manufacturing),
  - etc.



Content of Review SOPs

- General information on purpose, scope, responsibilities, etc.
- General instructions on preparing reports (e.g. which template to use, formatting, etc.)
- Scientific and regulatory instructions on preparing reports
- Links to report templates



STANDARD OPERATING PROCEDURE
(SOP Template Version 3.1: Effective Date 2011-10-01)

Title: [Title of Standard Operating Procedure]	**Doc. Number:** [Short code #] **Version:** [Version #] **Review Date:** [Date to be reviewed (usually 2 years) yyyy-mm-dd]

Bureau / Office: [acronym] **Area:** [division or group]	**Status:** [in development/draft/final] [in development/draft date]	**Effective Date:** [Date for coming into operation, yyyy-mm-dd]

Approved by: [Name] [Title]	**Signature:**	**Approval Date:** [Date signed by Approver, yyyy-mm-dd]

Health Canada Santé Canada

Therapeutic Products Directorate
Direction des produits thérapeutiques

To/A:	[Name], Director [Bureau]
From/De:	[Name(s)], [Reviewing Division] [Bureau]

Security – Classification – de sécurité: Protected B when completed
Date: [Completion date of the report.]

Subject/
Objet:

[Title of Template]

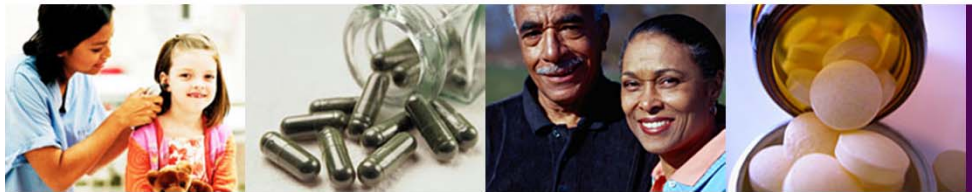
[code and version number: Effective date: [yyyy-mm-dd]

Brand or Product Name of Drug Product		
Proper or Common Name of Drug Substance		
Manufacturer / Sponsor		
Therapeutic Classification		
Dosage Form(s) and Strength(s)		
Route(s) of Administration		
Type of Submission		
TPD Target Date		
Control Number / File Number		
Date NOC/c Issued / International Birth Date		

Parts of Submission Reviewed in this Report	
Review Period	
Reviewer Recommendation	

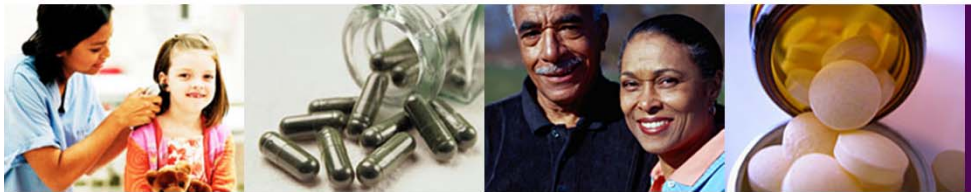
Examples of SOPs

- Preparation of the Scientific Review Report for Medical Device Licence Applications
- Using the Pharmaceutical Safety and Efficacy Assessment Templates (PSEATs) to Prepare Reports on Submissions for Marketing Authorizations



Review Reports

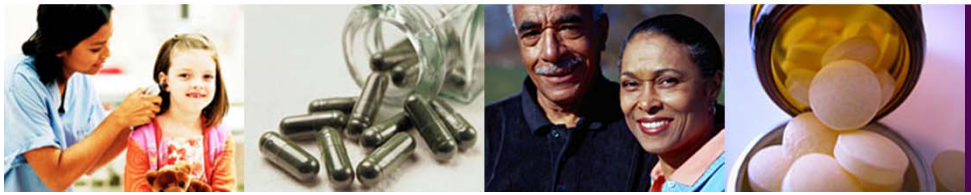
- All review reports are prepared using the report templates, following the instructions in the associated SOP (*Do What You Say*)
- Managers read the review reports and make final recommendations on the applications



Auditor General Findings, Fall 2011

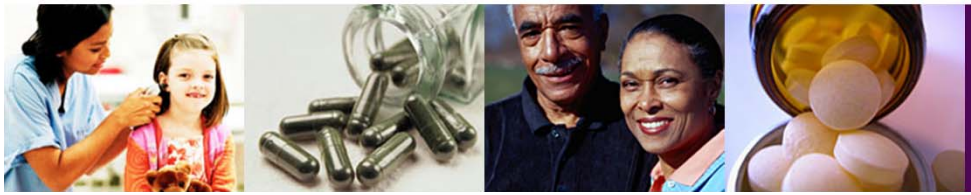
"We found that the Department has the following key components of a quality assurance system:

- standard operating procedures,
- guidelines for drug reviewers,
- review templates,
- training programs, and
- management review of individual files."



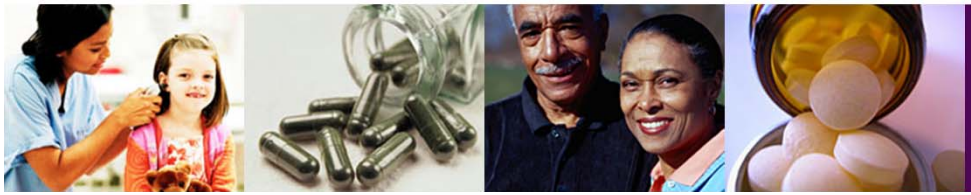
Auditor General Findings (2)

"However, we also found that Health Canada has not assessed whether review procedures, guidelines, and templates were consistently interpreted and applied across the four different review bureaus responsible for conducting reviews of drug submissions."



Auditor General Recommendation

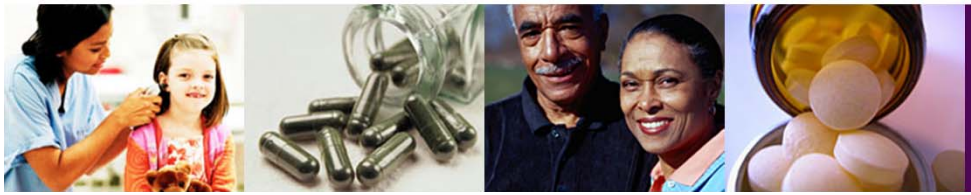
"Health Canada should regularly assess whether the procedures and guidelines, which were established to ensure timely, consistent, and high quality review decisions, are interpreted and applied consistently by all four review bureaus."



Health Canada Response

"The Department will develop a system to regularly assess and ensure the use of procedures…
by 31 December 2012.

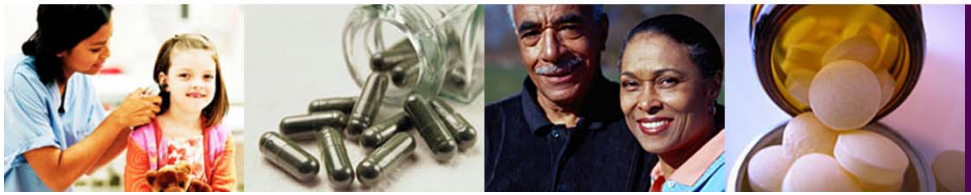
Implementation of the system, which will include assessment of compliance with procedures and consistency of interpretation…and necessary corrective mechanisms…will be completed by 31 December 2013."



Developing the System

Health Canada's new SOP Audit Program contains

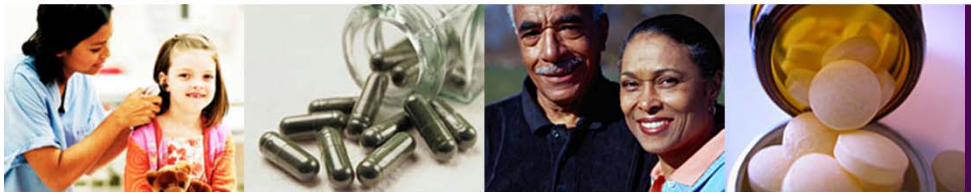
- the objectives of the program,
- the roles and responsibilities of the program manager,
- the scope of the program (i.e. review SOPs).



Developing the Plan

We are currently developing our PSEAT SOP Audit Plan, which will contain

- audit scope and objectives,
- criteria for evaluation,
- schedule and sampling strategy,
- reporting strategy *(Prove It),*
- approval and monitoring strategies *(Improve It*).



Health Canada Regulatory Review

- ✓ Say What You Do
- ✓ Do What You Say

And coming soon:

- Prove It
- Improve It