



Update from the IGDRP Biowaivers Working Group

IGDRP-EDQM Workshop
Strasbourg, France
13 May 2016

Dr. Craig Simon
Associate Director,
Bureau of Pharmaceutical Sciences
Therapeutic Products Directorate
Health Canada



Outline

- Background
- Current projects
- Past projects



Background

- Created in May 2013
- Face to face meetings twice a year
- Regular teleconferences between face to face meetings
- Co-Chairs – Health Canada and WHO



Background

- Mandated objective:
 - Survey and collate information from each jurisdiction regarding types of acceptable biowaivers and the requirements for each. This information will be distributed via publication in scientific journals and on the IGDRP web site. Where appropriate develop tools (e.g. assessment templates, guidance for assessors) to aid in assessment of biowaiver requests.



Current Projects

- **Survey of BCS biowaiver requirements-Publication of Manuscript**
 - Survey complete
 - Initial draft of Journal article prepared
 - Next steps
 - - revise article to incorporate comments from WG
 - - Publish on IGDRP web site, in journal, or both
- **Documentation to support a request for a BCS based biowaiver**
 - Location within CTD for required information
 - WG to develop recommendations
 - IGDRP to forward recommendations to ICH for their consideration.



Current Projects

- **Waivers for additional non-biostudy strengths**
 - Initial survey complete
 - Draft journal article summarizing requirements for immediate release products prepared
 - Next steps
 - Update and clarification of responses
 - adjustment of survey questions
 - validation of input
 - preparation of manuscripts describing similarities and differences amongst regulators for modified release and delayed release products



Current Projects

- Tracking new BCS classification decisions
 - Create ongoing project
 - Standing item for teleconferences and meetings to update spreadsheet capturing these decisions
- Acceptability of Foreign Comparator
 - Survey completed
 - Draft summary prepared
 - WG to provide comments on narrative summary and any updates to requirements



Current Projects

- Biowaivers for Dosage Forms
 - Dosage forms covered:
 - Oral solutions, IV solutions, IM and SC solutions, Emulsions for injection, Inhaled products, Topical products, Suppositories, Otic/ophthalmic
 - Next steps
 - Update of survey information by WG members
 - Clarification of responses and questions
 - Prepare a summary of similarities and differences

New Projects

- Assessors guide for biowaivers for additional non-biostudy strengths.
 - New project
 - Proposed format is assessment template containing guidance to assessor in each section.
- Approach to selection of alternate reference/comparator product
 - New project
 - Survey of approach used by members to select an alternate reference/comparator product when the original reference is no longer marketed.

Past Projects

- BCS Biowaiver Assessment Report
 - Report template created for use by Assessors
 - Also provides guidance to assessors
 - Successfully tested by members of the working group in the assessment of BCS biowaiver requests.
 - Use is ongoing.
 - Investigating posting of template on IGDRP website.
- Classification of list of drugs according to BCS
 - Changed to ongoing project to collect BCS decisions as they are made by members.



Future

- Potential to expand the scope of the mandate of the working group
 - Although there is ongoing work to complete existing projects on biowaivers, the group has expressed interest in pursuing projects that fall outside of the biowaiver area.
 - There has been frequent discussion at the working group meetings during of bioequivalence related issues encountered by the members that are not biowaiver related.
 - Will explore expansion of scope to include greater number of bioequivalence issues.

Thank you

