

Module 8: Data for Abridged Applications and Specialised Products
20th – 22nd January 2021



Location: Online – time is GMT (CET+1)

Module Leader(s): Alenka Dražumerič and Eva Kopečna

Date: Wednesday 20th January 2021

Chairperson: **Alenka Dražumerič**

Time	Activity	Speaker
08.45 – 9.00	Registration Welcome & Introduction to the Module Learning objectives	Module Leaders
09.00 – 10.00	Lecture 1: Revision of Regulatory Strategic Issues for Abridged Applications - A Regulatory Agency's Experience Legal basis Definition of generics Intellectual property Regulatory procedures Paediatric regulation Submission strategy	TBC MHRA
10.00 – 11.00	Lecture 2: CMC Drug Substance – Established Molecules CEPs, DMFs Physicochemical properties Setting drug substance specification Manufacturing issues for drug substance Containers Stability requirements TSE Specific data requirements for other regions, i.e. LATAMA/APAC	Mojca Ule Sandoz
11.00 – 11.30	Refreshment Break	
11.30 – 12.30	Lecture 3: CMC Data Requirements: Drug Product Line extension with different dosage forms Generics product development and manufacture Specifics of modified release, topical products, injections Setting drug product specification Stability requirements Common deficiencies Inspections Specific data requirements for other regions, i.e. LATAM/APAC	Alenka Dražumerič Medis
12.30 – 13.30	Lunch	
13.30 – 14.30	Lecture 4: Bioequivalence Pharmaceutical equivalence Therapeutic equivalence Design of bioequivalence studies Biowaiver Choice of reference and test products Review of the revised guideline on bioequivalence	Dejan Krajcar Sandoz

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14.30 – 15.30 Lecture 5: **Non-clinical Considerations: Abridged Applications and Testing Strategies** Michelle McDonald
Parexel
Bridging Tox
Combination products
Paediatric indications
Novel excipients
Environmental Risk Assessment

15.30 – 16.30 Lecture 6: **Clinical considerations** Rozeta Mileva-
Peceva,
ALKALOID AD
Skopje
New Indications
New Routes of Administration
Additional dosage forms
New target population
Paediatric indications

Date: Thursday 21st January 2021

Chairperson: **Eva Kopečna**

Time	Activity	Speaker
08.45	Registration	
09.00 – 10.00	Lecture 7: Abridged Options US Abbreviated NDAs Supplementary NDAs 505(b)(2) applications Influence of ICH in the US Role of the FDA and recent developments (i.e. fees, ObD)	Sarah Roberts PRA Health Sciences
10.00 – 11.00	Lecture 8: Drug Device Combinations Definition (Medicinal Product/Medical Device) Medical Device legislation Regulatory approval process Drug/Device products (borderline products, medicated devices, drug delivery systems, drug device combinations)	Mark Chipperfield Corvus Device
11.00 – 11.15	Refreshment Break	
11.15 – 13.00	Case study 1	Module Leaders
13.00 – 14.00	Lunch	
14.00 – 15.00	Lecture 9: Blood Products What are blood products? Master files Albumin as an excipient	Benedicte Deloux Bio Products Lab Kay to contact on behalf of Alenka
15.00 – 16.00	Lecture 10: Inhalation Products Product types (nebulisers, MDIs, DPIs) Quality/Safety/Efficacy Product information (SmPC, labelling)	Mike Bateman Diurnal Ltd.

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Date: Friday 22nd January 2021

Chairperson: **Alenka Dražumerič**

Time	Activity	Speaker
08.45	Registration	
09.00 – 10.00	Lecture 11: Radiopharmaceuticals What are Radiopharmaceuticals? Examples of Radiopharmaceuticals use Radiopharmaceuticals legislation Manufacturing challenges Specifics of Quality/Non-clinical/Clinical data Product information (SmPC, labelling)	Peter Bradley GE Healthcare
10.00 – 11.00	Lecture 12: Herbals Overview of legislation for herbals Registration routes: Well established use, traditional use Specific requirements for herbals: Quality, Safety, Efficacy	Reinhard Länger AGES
11.00 – 11.15	Refreshment Break	
11.15 – 13.00	Case study 2	Module Leaders
13.00 – 14.00	Lunch	
14.00 – 15.00	Lecture 13: Cosmetics EU Requirements of the Cosmetic Regulation Ingredients & manufacture requirements Responsible Person & Product Information File Cosmetic Notification Labelling & Cosmetovigilance Cosmetic vs. Medicine – borderline issues	Tamsin Worrad- Andrews Unilever
15.00 – 15.15	Summary and Closure of Module	Module Leader
