Healthcare Product Specialists' **Education Elements** are modules that you can select as required to enhance your compliance activities and take advantage of regulatory opportunities. Education Elements are charged per session. You are welcome to have as many (or few) colleagues attend at no extra charge.

It's education for product development.

More power to you.

Regulatory Basics

4 hours - $985

- Who are the TGA, FSANZ and AICIS, and what do they do?
- Legislative overview.
- Product classifications.
- Where to look for information.
- Relationship management tips.

Evidence Development

4 hours - $985

- Why develop evidence?
- Legislative overview.
- Key principles of evidence development, including locating evidence, evidence classification and requirements, indication classification and requirements, presenting evidence, critical appraisals & justifications.

Advertising Compliance

2 hours - $495

- Legislative overview.
- Listed medicines vs. foods.
- Key aspects of the Therapeutic Goods Advertising Code, including mandatory information, endorsements, testimonials and warnings.
- Problematic claims and their consequences.

Labelling - Foods

2 hours - $495

- Mandatory inclusions.
- Nutrition Information Panel (NIP).
- Ingredient list requirements.
- Allergen declaration.
- Nutrition & Health Claims.
- Country of origin requirements.

Labelling - Medicines

2 hours - $495

- Design requirements.
- Mandatory inclusions.
- Ingredient declaration requirements.
- Allergen declaration.
- Indications & Claims.
- Country of origin requirements.

ARTG Listings

2 hours - $495

- What is eBS.
- How to navigate and find key information.
- Code tables.
- How to create a new listing.
- How to update an existing listing.
- Section 9D changes.

Specifications

2 hours - $495

- How to read and understand a specification.
- Raw material specification evaluations.
- Preparing specifications.

Formulation

4 hours - $985

- Formulation principles.
- Formulating to achieve desired claims.
- Choosing ingredients and packaging.
- Formulating to the regulatory category.
- Dosage form nuances- powders, capsules, tablets, liquids etc.
- Choosing your manufacturer.
- Understanding Cost of Goods (COGs) and mark ups.
- Dosing and directions for use.
- Batch sizes.

Pharmacovigilance

2 hours - $495

- Key principles of pharmacovigilance – navigation of Australian and EU legislation and the interaction between them.
- Pharmacovigilance responsibilities of medicine sponsors.
- Reporting adverse events.
- TGA's Pharmacovigilance Inspection Program.
- Safety assessments and how this impacts product development.

Healthcare Product Specialists

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