Regulatory Risks are Investment Risks You Can Mitigate

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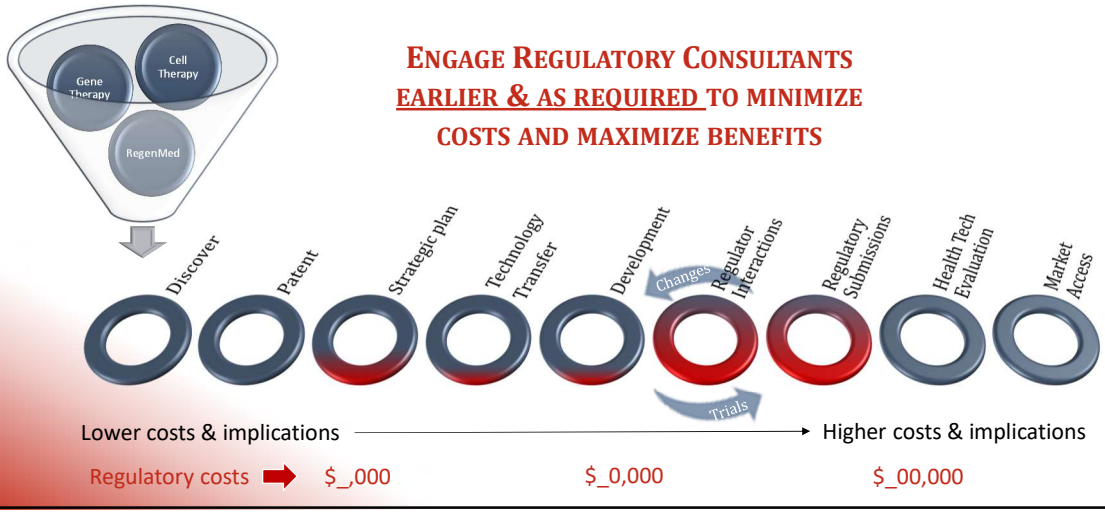
weCANreg Wants to Help You at Several Points in Development

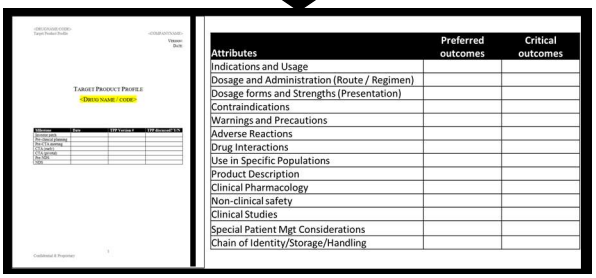


4

Education & Strategic Planning Services

Improve your plans by challenging them with Regulatory knowledge and expertise:

- weCAN use regulatory information to provide **customized educational workshops** & augment **strategic development plans**
- Our **planning checklists** can (and should) be used to help assess or justify investment requests



TARGET PRODUCT PROFILE
‹DRUG NAME / CODE›

Attributes	Preferred outcomes	Critical outcomes
Indications and Usage		
Dosage and Administration (Route / Regimen)		
Dosage forms and Strengths (Presentation)		
Contraindications		
Warnings and Precautions		
Adverse Reactions		
Drug Interactions		
Use in Specific Populations		
Product Description		
Clinical Pharmacology		
Non-clinical safety		
Clinical Studies		
Special Patient Mgt Considerations		
Chain of Identity/Storage/Handling		

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Education & Strategic Planning Examples

Planning & Education
Actvity
Clinical Planning
Seminar: Developing your Target Product Profile (TPP)
Facilitated Workshop: Developing your TPP
TPP Gap Analysis / Development
CMC Planning
Seminar: Developing your Quality Target Product Profile (QTPP)
Facilitated Workshop: Developing your QTPP
Quality Plan Gap Analysis / Development
Human Starting Materials Gap Analysis
RegenMed Clinical Trial CMC Gap Analysis / Development
Trial Planning
Seminar: Orientation to Canadian Regulations
Early trial Gap Analysis / Development

Detailed estimates will be provided in a proposed Statement of Work, once weCANreg has been able to discuss your needs with you and / or review confidential information.

Estimates will vary, depending on the status and complexity of materials and issues.

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Regulator Interaction Services

Approach the Regulator with confidence and clear purpose:

- weCAN use our Canadian-specific templates, extensive knowledge of Canadian policies, and niche experiences to **resolve complex issues** associated with emerging therapies, and **support productive interactions** with Health Canada

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Regulator Interaction Examples

Issue Resolution
Actvity
Issue Assessment & Resolution
Issue Orientation & Identification
Relevant policy discovery & assessment
Policy interpretation & documentation
Issue resolution & next steps
Regulator engagement for confirmation

Pre-CTA Interaction
Actvity
Request Materials
Meeting Request Letter & Related Interactions
Briefing Materials
Briefing Book Review & Development
Presentation Deck Support & Development
Meeting Materials
Meeting Attendance
Minutes Development

*Detailed estimates will be provided in a proposed Statement of Work, once weCANreg has been able to discuss your needs with you and / or review confidential information. Estimates will vary, depending on the status and complexity of materials and issues.

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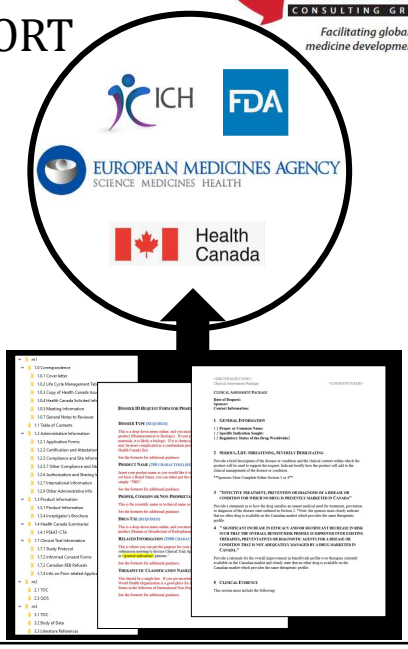
Regulatory Submission Support

Facilitating global regenerative medicine developments in Canada

Accelerate and improve your Regulatory submissions:

- weCAN **kick-start regulatory submission preparations** using templates that are annotated and formatted to accelerate their development, and **assess / augment existing documents** using checklists and niche experiences in cell & gene therapy



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Basic Clinical Trial Application Support
Actvity
Module 1.0 (Correspondence) Subtotal
Cover Letter
Copy of Health Canada Issues Correspondence
Health Canada Solicited Informatioin
Meeting Information
General Notes to Reviewer
Module 1.2 (Administrative Information) Subtotal
Application Forms
Certification and Attestation Forms
Compliance and Site Information
Clinical Trial Site Information Form
Other Compliance and Site Information Documents
Authorizaiton for Sharing Information
International Information
Other Administrative Information
Module 1.3 (Product Information) Subtotal
Product Information
Investigator's Brochure (checklist review / development)
Pharmacovigilance Information
Other Pharmacovigilance Information
Module 1.4 (Health Canada Summaries) Subtotal
PSEAT-CTA
Module 1.7 (Clinical Trial Information) Subtotal
Study Protocol (checklist review / development)
Informed Consent Forms (checklist review)
Canadian Research Ethics Board (REB) Refusals
Information on Prior-related Applications
Module 2 (QOS) Subtotal
Quality Overall Summary (DS) (checklist review / development)
Quality Overall Summary (DP) (checklist review / development)
Quality Overall Summary (Appendices) (checklist review / development)
Module 3 Subtotal
Literature references Subtotal
Literature references

Submission Support Examples

Facilitating global regenerative medicine developments in Canada

*This example assumes a Study Protocol and QOS have been drafted (potentially using weCANreg Annotated Templates), and require minor revision only.

Detailed estimates will be provided in a proposed Statement of Work, once weCANreg has been able to discuss your needs with you and / or review confidential information.

Estimates will vary, depending on the status and complexity of materials and issues.

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ENGAGING WECANREG

1. Reach out to weCANreg via email (patrickbedford@weCANreg.ca)
2. Discuss your regulatory needs AND/OR enter into a confidentiality agreement that allows you to share information for review
3. Agree to a proposed Statement of Work with clear tasks and deliverables that make sense to you, and state your preference to proceed on an hourly-basis or project-basis
4. Sign a Professional Services Agreement, with the Tasks and Deliverables and Work Schedule appended
5. Receive your services and provide feedback!

OR

Simply ask us a question – we love to solve problems!

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BRIEF BIO – PATRICK BEDFORD

(FOUNDER & PRINCIPAL CONSULTANT)

- Multi-disciplinary background (Honours Bachelor of Health Sciences, Master's of Bioethics and Health Law, Regulatory Affairs Certificate)
- Led Health Canada Projects (10 years)
  - Developed submission requirements for biosimilars
  - Supported transplant establishment regulation & inspections
  - Led all cell & gene therapy regulations policy initiatives
  - Represented Health Canada internationally (clusters / IPRP)
- Initiated regulatory services for CCRM (2 years)
  - Encouraged Canadian innovation
  - Supported global entry into Canada
- Planned Celgene CAR T New Drug Submissions (2 years)
  - Advised Canadian commercial launch team plans
  - Collaborated with global teams to develop submission strategy/materials

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