Raz Eliav

CMC Development and Regulatory Affairs Consultant

I am an expert in Biologicals CMC, and have worked with companies at all clinical stages.
Over the years, I have come to realize that CMC in the world of Biologicals is better described as BMD: Biology, Manufacturing, Design- which is a step Beyond CMC.

Contact

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Website
BeyondCMC.com

Services

- IND Readiness for FIH Clinical trials, Phase 2 and Phase 3
- Phase-appropriate CMC Development strategy and consulting
- Establish and manage outsourced operations with CDMOs
- CMC Regulatory Affairs - Submissions and interactions
- CMC Gap-assessments and Due Diligence support
- CMC and RA Training / mentoring
- CMC Mindmapping- to streamline onboarding and outsourcing
- Digital Transformation Kickstarter (coming soon)

Products

- Free course: Introduction to Drug Development and CMC
- Mini-course: CTD Module 3
- The CMC Essentials Training Course

Education

2005
B.Sc., Biotechnology Engineering
Technion- Israel Institute of Technology

2009
M.Sc., Molecular Genetics
Weizmann Institute of Science, Israel

Experience

2021- Present
Beyond CMC
Founder and Consultant

I started Beyond CMC with a mission to curate knowledge and Know-hows on Drug development and CMC, and offer training courses to industry professionals.

As a freelance RA/CMC consultant, I help companies at different development stages and of diverse product modalities with their RA and CMC development needs. This includes:

- Establish and operate a **phase-appropriate CMC** development strategy
- Science and Risk-based **CMC troubleshooting**- accommodating the "right thing to do" with the Startup reality and constraints
- Assistance with **CMC operations**: CMO selection, process development studies, etc.
- **Regulatory submissions and meetings**- authoring, review and strategy

Orasis Pharmaceuticals is my current lead client, where I help in preparations for commercial supply after having **compiled major parts of their New Drug Application**.

2019-2021
ADRES- Advanced Regulatory Services Ltd.
Director, CMC and Regulatory Affairs

ADRES is a consulting firm which provides QA, Regulatory and CMC consultation services. As the Director of CMC and Regulatory affairs, I managed a team of Regulatory professionals handling **regulatory submissions and interactions** with authorities in Europe, USA, Israel and China and helped developing **regulatory strategies for novel therapeutic**s. I lead our CMC services portfolio, which included **hands-on operational CMC management** of a wide range of product classes, such as Plasmid DNAs, Cell therapies and ATMPs, Viral vectors, Liposomes, Recombinant proteins, botanical products, etc.

2012-2019
Anchiano Therapeutics Ltd. (Formerly BioCancel)
CMC Manager

Anchiano developed a Plasmid DNA product for the treatment of Cancer, until the project was terminated mid-Phase 3 due to disappointing clinical outcomes.
I was in charge of all the **CMC operations**- from selection, negotiation and daily **management of CMOs** worldwide, **process development** of Biological DS's, aseptic processes and lyophilization, and countless **regulatory submissions, interactions and meetings**. These projects spun across all pipeline development (Preclinical to Phase 3) and included the careful balance of multi-million dollars **budgets, clinical supply and cross-functional management.**

2011-2014
ADRES- Advanced Regulatory Services Ltd.
CMC Consultant

In this role I assisted a multitude of companies in CMC and Regulatory activities, including authoring CMC-related regulatory submissions to FDA and EMA (INDs, pre-INDs, briefing packages, IMPDs, etc.), research for regulatory strategies, and other CMC related documentation such as development reports, comparability protocols and reports, etc. This has also taught me black-belt level Microsoft Office skills (Word, Excel, Project) and **professional document publishing techniques.**