

Consultancy – at every level

Eden Biodesign is much more than a contract development and manufacturing organisation: We provide expert consultancy to help you meet your development milestones more quickly and effectively.



Track Record

Drawing from an established track record of over seven years, Eden's consultancy business has built a recognised and respected reputation through working with over 75 clients worldwide. Our customers include academia, start-ups, biotech companies, large pharma, investors and government.

Our manufacturing and regulatory know how is backed by our rapidly growing process development and clinical manufacturing business which ensures we can draw on a large team of technical specialists – proven experts in their particular fields.

Experience

Having worked on virtually all types of product, processes and projects, from early technical feasibility to regulatory dossier submissions, Eden's consultancy has an unrivalled depth of knowledge backed by professional consultants who are recognised as some of the most experienced in the industry.

Clear and accessible consultancy

Whether you're an emerging biotech or a global pharma, Eden's consultancy support will provide you with the guidance and advice you need to successfully achieve your development goals. We understand the challenges and pitfalls inherent in drug development and the direction to take to keep you firmly on the path to success.

■ We begin with the end in mind

So what can Eden Biodesign consultancy services do for you?

Strategic advice

Eden Biodesign has provided strategic development advice for:

- Biopharmaceutical due diligence
- Facility design and operation
- Product development manufacturing planning
- Review of regulatory issues, cost of goods and quality implications

Training

Tailored training courses at Eden Biodesign or at client's facilities.

Examples include:

- Moving from research into development
- Overview of Product development
- Analytics and specifications for development
- Outsourcing cGMP manufacture
- Packaging and labelling to cGMP guidelines
- Introduction to regulatory affairs

Regulatory

Our activities within Product Chemistry, Manufacture and Analytical Control (CMC) Regulatory Affairs include:

- Development of regulatory strategies for successful submission and approval
- Review/evaluation of data for licence application
- Dossier compilation (ICH M4Q) for clinical trials and market authorisation
- Organisation and formal support at meetings
- Compilation of scientific advice packages
- Organisation and compilation of response packages

Specialist scientific advice and support

In the areas of statistical evaluation, bioassay, virology, analytical characterisation, production strategy, method development and validation

- Cell expression systems
- Analytical Development, QC and Validation
- Process Development
- Manufacturing and Compliance

Clinical trial supply

Services include:

- Management of supply logistics
- Advice on packaging and labelling design
- Sourcing and selection of specialist packaging companies, couriers and translators
- Sourcing of comparator products and clinical packaging solutions
- Preparation of compliant CTS documentation



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Case Studies

For more information on precisely how we have helped our clients, please visit our website to review our case studies:

www.edenbiodesign.com/4_2case.htm

These include:

- Clinical trial supply management for a major European pharma
- Process development advice and management for a European biotech SME
- Due diligence on a successfully licensed product for a European biotech SME
- Facility compliance consultancy for a major US Biopharma
- Gap analysis, expert advice and compilation of a BLA for a European pharma
- Development and cGMP training for a European pharma
- cGMP manufacturing training for Japanese SME

Contact us

If you're looking for the best professional advice and guidance from an established team of experts who have done it before, Eden consultancy aims to exceed your expectations; providing the precise answers you need in a timely and exacting manner.

Why not contact us to arrange a meeting?

– we're always happy to discuss possibilities and help you explore options.

Dr Richard Dennett

Head of Consultancy Services

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