CONSULTANTS & ADVISORS FOR UNIVERSITY SPIN-OUT PROJECTS: LIFE SCIENCE

Technology
Transfer Office

BUILD AN INNOVATIVE TEAM

Commercialisation of inventions demands more than scientific data and a patent application. Therefore, **the TTO business development team** introduces the following advisors to help AU inventors add **key capabilities** to their project.

We hope this list serves as an informative example. If you are a AU inventor and wish to contact one of these consultants or feel your future spin-out needs different capabilities - **please contact us – we are happy to help you**!

The TTO Business Development Team
Email: tto@au.dk Web: tto.au.dk

DISCLAIMER

This presentation is designed to educate Aarhus University researchers on the range of consultants that exist within drug discovery consultancy. It should not be regarded as any form of recommendation for any consultant in any form.

Aarhus University does not accept any liability regarding the work of any such consultant as described. This is not an exhaustive list and other consultants may be engaged.

KEY TERMS TO KNOW

We have highlighted key terms that you may wish to learn to help your discussions with advisors.

Regulatory Affairs – Regulatory affairs is a profession developed by governments to protect public health by controlling the safety and efficacy of products in areas including pharmaceuticals and medical devices

CE-marking - defined as the European Union's mandatory conformity marking for regulating the goods sold within the European Economic Area since 1985.

Toxicologist - professional who has studied toxicology and works with materials and chemicals to determine toxic effects they may have on environments and living organisms.

IP or IPR – Short-hand for Intellectual Property i.e. patent application, copyright or trade secret

Legal counsel – person employed by an organisation and works "in-house", whilst a lawyer is employed by a law firm.

Life cycle management - refers to product management as it moves through its product life: development and introduction, growth, maturity and decline.

Market analysis & strategy - provides information about industry, customers, competitors and other market variables. Strategy uses analysis to propose a set of activites to obtain sustainable competitive advantage in the market.

Consilia

REGULATORY: FINN MØLLGAARD

- MSc Pharm by training
- 34 years in pharmaceutical industry – regulatory affairs (24 years at Novo Nordisk A/S)
- Experience from all phases of development from early projects through to life cycle management
- Member of Novo Nordisk's Research Portfolio Board responsible for governing the transition of projects from discovery into development
- Global experience - multiple agency interactions
- Leader of groups up to 175 employees

Consilia is a consulting company established in 2018 offering regulatory and drug development counselling primarily to small and medium-sized and start-up companies during early development.

medídee®

REGULATORY – MEDTECH: PETER SIELJACKS

- Regulatory strategy and pathway development for CE-marking and FDA approval
- Preparation of Technical Documentation for CE submission
- Clinical strategy and pathway development for CE-marking and FDA approval
- Development of Software as a Medical Device
- Clinical Investigation design, monitoring and audit
- Coaching in Design & Industrialization

Since 2013 Medidee offers consultancy services in Quality Assurance, Regulatory & Clinical Affairs and Digital Health. We are more than 50 consultants supporting MedTech companies of all sizes, from idea to market.

PRECLINICAL TOXICOLOGIST: ANDY MAKIN

40 years in Preclinical Toxicology in UK and Denmark

MSc (Applied Zoology), Registered Toxicologist

Andrew Makin Preclinical Consulting ApS is a consulting company established in Denmark in 2019 that offers advisory and consultancy services to any company developing pharmaceuticals, medical devices and other products in the stages prior to clinical trials or marketing. Based on experience gained through nearly 40 years working for Contract Research Organisations (CROs), during which time I have acquired a comprehensive knowledge of programme and study design, performance, interpretation and reporting, I have a fundamental understanding of the needs of drug and other product development, and practical experience of putting knowledge into practice.

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www.andrewmakin.dk

Daring Bio

MEDICINAL CHEMIST: GRAHAM SIMPSON

- **Univ of Strathclyde** – BSc Hons Org Chem – 1995-1999
- **Univ of Bristol** – PhD Organic Chemistry – 2000-2004
- **M.I.T** – Fulbright/1851 Commission Postdoc – 2004-2006
- **GlaxoSmithKline MRC UK** – Medicinal Chemist, Chemistry Team Leader, Project Leader, Head Therapeutic Peptide and Technology Platforms – 2006-2018
- **GTN Ltd** – Head of Drug Discovery and Partnerships - AI/ Deep-Learning startup – 2018-2019
- **Daring Bio Ltd** - Independent Consultant - 2019-2020

Daring Bio Ltd is a consulting company established in 2019 working with biotech companies in the UK and Europe, as well as venture-capital investors in the US carrying out due diligence, advising on project strategy and leading specific medicinal chemistry projects.

- Expert knowledge in small molecule, peptide and PROTAC therapeutic modalities
- Experienced medicinal chemist and programme leader across target classes and therapeutic areas including oncology, immune/inflammation, infectious diseases, metabolic and respiratory
- Wide knowledge and use of platform technologies for target identification, target validation, hit finding, lead optimisation and drug delivery

marigold innovation

COMMERCIAL: MARIGOLD

Peter Horn Møller, Founder & CEO

Expertise: IP, licensing, strategic business development and partnerships

Niels Skjærbæk
Senior Advisor

Expertise: Business Development, drug development, commercialization

Camilla de Thiersant
Co-founder & Partner

Expertise: Commercial, strategy, business plans and execution

Services:
IP Licensing
Legal
Market strategy & business plan
Funding & strategy
Leadership
Business Development
Partnerships
Project Management

LEGAL ADVISOR: URSUS LAW FIRM

- Ursus law firm is a law firm dedicated to assist the European biotech and pharmacy industry. The owner, Søren S. Skjærbæk, has more than 20 years of experience from private law firms and as both in-house and external legal counsel to multiple listed biotech companies.
- The law firm is primarily serving clients in the European biotech and pharmaceutical industry but also acts as “in house counsel” for medium sized companies who do not have their own legal department.
- It is the goal of the law firm to provide value adding and straight-to-the-point legal advice with a strong focus on the business aspect of each case.

Main practices: License Agreements, Research and Development Agreements, Collaboration Agreements, Manufacturing Agreements, Patent Transfer Agreements, Distribution and Agency Agreements, Clinical Trial Agreements, Consultancy Agreements, Material Transfer Agreements and Confidentiality Agreements. Danish Company Law, Danish Employment Law, Mergers&Acquisitions and Commercial Legal Advice.

MENTORS: OPEN ENTREPRENEURSHIP @ AU

Jonas Brandt
Senior Consultant

Terese Kellenberger Hybschmann

Development Consultant

Open Entrepreneurship is a Danish initiative – based at AU, aiming to turn world-class research into world-class spin-outs.

Studies have shown that matching research teams with experienced and external entrepreneurs creates more sustainable businesses.

We will capture the value through an action-oriented approach by connecting experienced entrepreneurs with researchers very early on to explore commercial and innovative opportunities. These can either be entrepreneurial (spinout or startup company) or intrapreneurial (within the university, company or organization).