



QUEEN'S HOUSE CONSULTING

PHARMACEUTICAL AND HEALTHCARE CONSULTANCY



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About Queen's House Consulting Services

Queen's House Consulting is a UK-based pharmaceutical and healthcare consultancy, providing specialised services to bio/technology companies and healthcare providers. Formed in 2016, we draw on industry and public healthcare experience to advise on pharmaceutical product development from concept to lifecycle management and on the organisation/delivery of healthcare services.

This allows us to provide support which is tailored to our clients' individual requirements, which range from de novo projects and investment opportunities to highly focussed work orders requiring specialised skills for rapid completion. Queen's House Consulting works to satisfy every client with added value for their business operations, whether in the public, private or charity sector.

Queen's House Consulting can help clients to commercialise ideas and implement operational improvements in the following areas:

- translational science and start-up strategy
- due diligence
- pharmaceutical and healthcare process systems analysis
- biopharmaceutical pre-clinical development and technology transfer
- blood and plasma service
- regulatory authoring
- information Services

To find out how Queen's House Consulting can meet your particular needs,

contact: info@queenshouseconsulting.co.uk

or visit the website: <https://queenshouseconsulting.co.uk>

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Translational Medicine and Start-Up Strategy

As an academic or healthcare professional managing your routine workload, it can be challenging to map out the many steps needed for translation of your idea into a novel medical therapy.

Technical development, financing, intellectual property protection and regulatory compliance all require focussed capabilities, management and alignment for your invention to deliver the goal of a successful product.

The creation of an effective start-up company will also highlight the need to establish and maintain investor confidence in your development programme.

Queen's House Consulting can provide independent and confidential advice, based on expertise in delivering successful products from concept to market. This includes:

- independent assessment of your technology
- consideration of scientific and technical feasibility
- gap-analysis and work plan to satisfy the expectation of investors
- timelines for translation and implementation
- options for commercial- or open-access
- advice on strategy for robust and sustainable phased funding
- prospectus to explain your discovery and business opportunity
- confidential mediation with potential partners, stakeholders and adopters

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Due Diligence

The growth in biotechnology and biological sciences, along with encouragement for academic and healthcare institutions to commercialise novel discoveries, present new opportunities for investment, mergers and acquisitions.

Underpinning the headline financial offering is the technology itself. In a rapidly-changing scientific and regulatory environment there is a need to understand the realisable value of the target asset. As these opportunities can range from “me-too” products sharing an existing market, through disruptive technologies which re-define the market, to discoveries which create a completely new market, the balance of technical feasibility and fit with your own business objectives is particularly important.

Queen's House Consulting can provide independent and confidential advice to M&A and investment professionals, offering critique of scientific data and development prospects for biotech and biological therapeutics. This addresses elements from concept through laboratory to market launch:

- independent assessment of blue-sky discovery potential
- technical SWOT analysis of proposed and next-phase bio/tech start-up businesses
- gap-analysis of the offering and options to add value
- identification of realistic timelines and resource requirements to achieve technical gateway milestones

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Process Systems Analysis

Over time, delivery of services within any organisation can become increasingly complex. This erodes the original connection between individuals and corporate purpose, with a negative impact on the quality and quantity of their output. These effects are difficult for the organisation to identify, until their clients become dissatisfied with the service provided. The problem is common to both public and private sectors, affecting client confidence and revenues.

One remedy is to review working practices, identifying those processes which have evolved over time and undermine delivery. This allows re-engineering of the work-place for improved productivity, staff motivation and commitment to success. However, it can be difficult to complete such a review from within your organisation due to internal preconceptions. Queen's House Consulting is sufficiently detached to provide this service, while remaining anchored to the core experience of pharmaceutical and healthcare organisations. This ensures that your values and objectives are not sacrificed to a generic solution.

Queen's House Consulting offers an independent analysis of your operations, with solutions to achieve your required service level improvements:

- mapping your organisation's purpose, objectives and evolution
- defining strategy to satisfy corporate and individual aspirations
- engaging staff during workplace audit, without disruption of service delivery
- analysis of process-, systems- and work-flow to identify bottlenecks
- options to improve service delivery

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Pre-Clinical Development and Technology Transfer

The vibrant biopharmaceutical ecosystem offers a launch-pad for many ideas and inventions out of academic, public sector and commercial research. The creation of new companies to exploit those discoveries is underpinned by diverse funding arrangements and the availability of start-up incubator/catalyst facilities.

The transition from concept to pre-clinical development may present a challenge. Diverse skills are needed to cross this bridge, re-aligning creative and inventive skills to satisfy a different regulatory and commercial environment, while not undermining the founders' original intentions and expectations.

Moving through the development lifecycle, some out-sourcing and technology transfer of specialist services may also be needed, to deliver pre-clinical milestones or as part of a commercial licensing arrangement.

With operational experience of successful biopharmaceutical development, Queen's House Consulting can support the different stages of your programme:

- strategic plan with achievable outcomes
- process design, development and optimisation
- compliance standards appropriate to stage and scale
- risk management
- technical agreements with commercial partners
- technology transfer between the sponsor, suppliers and licensees
- engagement with regulatory authorities

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Blood and Plasma Services

Queen's House Consulting expertise provides 40 years of experience in the blood and plasma industries and is well-placed to support this specialised and highly-regulated part of the biopharmaceutical industry.

Queen's House Consulting offers a breadth of understanding from donor recruitment and retention, the handling of blood and plasma, the development and manufacture of blood/plasma products, to product lifecycle management, all within a regulatory framework focussed on product quality and patient safety.

This provides clients with a holistic input to any project, adding value whether you are focussed on one particular step or considering the complete supply chain.

Queen's House Consulting can advise clients on a range of topics within the blood and plasma industries, including:

- blood and plasma collection
- plasma quality
- pathogen safety
- fractionation technologies and efficiency
- blood/plasma-derived therapeutic and diagnostic products
- socio-economic considerations

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Regulatory Authoring Services

The authoring of pharmaceutical regulatory dossiers can make disproportionate demands on staff whose unique specialist expertise is also needed to support to other business objectives. Whether documentation is needed for preliminary scientific advice, clinical trial applications, marketing authorisation applications or responses to health authority questions, there is often an urgency which can over-burden your own resources.

Queen's House Consulting can relieve that workload, providing experienced technical authoring skills for Quality and Non-Clinical dossiers, while your experts retain ownership of their discovery.

Working to your specifications, Queen's House Consulting can provide:

- application documents for orphan drug designation
- critical questions for scientific advice meetings
- scientific advice meeting pre-read briefing materials
- transformation of raw data and internal reports into clear English narrative with tabulation and graphics
- investigational medicinal product dossier (IMPD) for clinical trial applications
- ICH CTD Modules 2 (quality & non-clinical), 3, and 4 for marketing authorisation applications
- strategy and authoring for responses to health authority requests for information (RFI)
- completion reports for CTD M3 and M4 post-marketing commitments

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Information Services

Communication of complex scientific, pharmaceutical or healthcare concepts to the non-specialist is essential to secure their understanding. With understanding comes confidence; with confidence comes support.

The need for effective communications exists whether you work in the academic, public or commercial sectors of bio/tech and healthcare. Good communication can enhance the reputation, public policy, consent and future investment confidence which ultimately reinforce your own work.

At the same time, it can be difficult to present specialist topics within your own expertise in a forum comprising different skills, experience and viewpoints. It is often helpful to optimise your message with an informed but detached third party, before conveying it to the target audience.

Queen's House Consulting can help you enhance the communication of your work, tailored to different audiences:

- identifying and consolidating key messages
- making complex concepts accessible to non-experts, without loss of technical integrity
- creating information documents, briefing papers and media releases
- providing technical authoring advice to subject matter experts in the scientific, pharmaceutical and healthcare sectors

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