

DAVID HOWLETT
3 Low Road Grimston King's Lynn Norfolk PE32 1AF
+44 (0) 1485 600065 mobile +44 (0) 7789 900750
david.Howlett@pharmadelivery.com
Date of birth: 31st July 1959
Passport: British

Highly skilled Technical Consultant with first class knowledge in 'leading edge' technologies used in the drug delivery device market.

Skilfully addresses the critical success factors of technical innovation and enterprise.

David Howlett is the founder and principle consultant of PharmaDelivery Solutions Ltd a successful, dynamic consultancy supporting the development of drug delivery systems at all stages.

KEY AREAS OF EXPERTISE

Technical and Engineering

Particularly sound technical skills with an excellent working knowledge of 'state of the art' design, development and manufacturing techniques used in the design of drug delivery devices and related systems i.e. pulmonary drug delivery systems, nasal delivery systems, medical check valves, and inspiratory flow controllers. Active leading technical role in a number of successfully launched CFC to HFA pMDI transition programmes, with international clients.

Extensive experience in a wide range of drug delivery technologies especially Dry Powder Inhalers (DPIs), Metered Dose Inhalers (MDIs), Novel Multi-dose Liquid Inhalers (MLIs), spray pumps, add on devices and nebulizers.

Considered expert in the field having over 30 patents, comprehensive publications record and a record of international technical Consultancy.

- § Recognized international expert in the field of respiratory drug delivery device technology when invited to present at high profile, international conferences and to participate in working groups to address leading edge, technological issues.
- § Honorary Teaching Fellow in the School of Pharmacy and Pharmaceutical Sciences at the University of Manchester and is tutor for the Pharmaceutical Industry Advanced Training module on Inhalation dosage forms.
- § A UK national expert on ISO TC84 WG5 developing new international standards for pulmonary and nasal delivery devices.
- § Extensive industry network facilitating optimisation of programs.
- § Highly developed data sourcing skills having created and managed data mining systems to ensure integrity of market and regulatory information.

Research Project Management

The ability to operate both tactically and strategically has underpinned a proven track record in the successful delivery of simultaneous, business critical projects. Highly skilled in the full project life cycle from concept, to sign off. Planning skills demonstrated when working within strict, non-negotiable deadlines.

- § Managed the industrialisation to supply of Phase III Clinical supplies of a new inhaler system to allow major Client to achieve target launch date, producing the most profitable product in Company's history, generating a significant income through subsequent years.

Successfully delivered within budget over an 18 month period, managing a team of over 35 internal technical staff and external contractors.

- § Managed the industrialisation from concept to supply of Phase II Clinical supplies of a new nasal Insulin delivery system based on novel device IP.
- § Sensitively handled the political, cross cultural issues and addressed the materials competence, performance assessment and analytical techniques of a self funded, valve development project.

Relationship Management

Well developed inter-personal skills have provided the platform for the building and maintaining of lasting business relationships to support not only the internal company framework but also sustainable business growth with customers.

Versatility and flexibility demonstrated when working with partnering organisations, changing direction and adapting to dynamic situations without losing sight of the commercial drivers.

- § Demonstrated ability to motivate, contribute and or lead multi-disciplinary teams, including multiple organization task forces.
- § Manages particularly well in creative and technically innovative environments, empowering individuals to achieve but also encouraging and motivating using a variety of techniques, especially coaching and mentoring. Creates harmonious working environments, promoting open communications to support technical challenges.
- § Tenacity in business development has been recognized allowing the successful managing technical development resulting in a fruitful partnership across multi-cultural divides.
- § Designed and developed various partnering arrangements with 3rd party suppliers (in such fields as nasal deposition modelling and novel nasal formulations) and customers applying strong commercial focus to secure optimum pay back and mutually beneficial conclusions.

CAREER SUMMARY

PharmaDelivery Solutions Ltd

Director

2003- current

Established PharmaDelivery Solutions Ltd as a highly specialised consultancy service in the field of drug delivery (especially respiratory) device technology. This has led to involvement in projects involving pulmonary, nasal and other delivery routes, with an international client base.

Much of the activity of PharmaDelivery Solutions Ltd is focused in the area of development programme support, regulatory GAP analysis and generation of development and test programmes, together with data review and contingency evaluation.

PharmaDelivery Solutions Ltd has developed already, a reputation for delivering to or beyond expectations ensuring that much of the current portfolio of clients base is multiple repeat business, or word of mouth referral.

Examples of typical activities include;

- Identification of "Best-fit" delivery technologies/ providers, to match therapeutic profiles and patient needs.
- Audit/ GAP analysis of Device Design Control procedures.
- GMP audits of/ for device and component suppliers.
- Audit/ review/ Advice/ GAP analysis on Device History Files.
- Audit/ Review/ Comment on Risk Management Strategies.
- Review/ establish risk management tools (dFMEA/ FTA).
- Audit/ Review/ gap analysis on Type III device Drug Master Files (DMFs)
- DMF design and preparation.
- Technical input/ reporting in support of due diligence activities.
- Program, pivotal independent technical reviews.
- Materials compliance review for international filing and supply strategies.

- Co-ordination of extractables and leachables activities between device manufacturer/ client/ contractor.
- Technical interface between device supplier and client from concept to industrial scale and/ or alternate sourcing.

More detail at www.pharmadelivery.com.

In addition to the above as a result of the activities in the field of inhalation drug delivery and device technology;

- Currently holds an appointment as Honorary Teaching Fellow in the School of Pharmacy and Pharmaceutical Sciences at the University of Manchester and is tutor on the MSc module on Inhalation Dosage forms.
- Is retained by UNDP as an International Technical Expert for assistance in plans to phase out Ozone depleting substances associated with Metered Dose Inhalers.
- Is retained as a consultant on a number of UNIDO co-ordinated programs in support of the Multilateral Fund for the implementation of the Montreal protocol.
- Is the nominated UK country expert operating on behalf of the British Standards Institute, assigned to the ISO Technical Committee 84 supporting the development of a new ISO standard (20072) for the design verification of inhalation devices.
- Has been an invited speaker to a number international conferences presenting on aspects of technology and regulation of inhalation devices.

Bespak plc

PRINCIPAL RESEARCH MANAGER PULMONARY/MANAGER TECHNOLOGY PARTNERING (2000 to 2003)

Responsible for the identification, due-diligence, evaluation and progression of new technology opportunities within the field of Drug Delivery through the following processes:

- collaborative research projects
- technology licensing
- acquisitions
- mergers

TECHNICAL MANAGER (1996-2000)

Responsible for the provision of an informed, internal technical Consultancy to the Commercial operations, covering new business development, techno-commercial negotiations, trouble shooting, PR and new technology evaluation.

MANAGER – INHALATIONS GROUP (1993-1996)

Responsible for the co-ordination of the technical capabilities within the pulmonary market including the following systems:

- metered dose inhalers
- dry powder inhalers
- novel technology

Key responsibilities for the programme interactions and input on CFC to HFA transition programmes with a number of major clients.

PRODUCT MANAGER (1990-1993)

Responsible for customer liaison of all aspects of programme management.

SENIOR DEVELOPMENT ENGINEER (1986-1990)

Managed a team of up to 4 Development Engineers responsible for the development of new drug delivery systems.

DEVELOPMENT ENGINEER (1980-1986)

Pye Electro Devices Ltd

1975 – 1980

PRODUCTION ENGINEER

Following the completion of Technician Apprenticeship was successfully retained. One of the first of 8 apprentices used to pioneer and refine the apprenticeship programme.

TRAINING AND DEVELOPMENT

QUALIFICATIONS

BA (Hons) Mechanical Engineering 1st Class

BA (Tech) Mechanical Engineering

HNC Mechanical Engineering

ONC Mechanical Engineering

ONC Electrical Engineering

C&G 200 Craft Course

Full indentured Technician Apprenticeship

COMPETENCIES

Highly computer literate, proficient in Microsoft Word, Excel, Power-point, Project and Access.

Capable with major graphics and imaging software and various forms of mobile computing and communication.

“Survival” level in Spanish, Italian, French and German.

PERSONAL DETAILS

Marital Status Married

Date of Birth 31st July 1959

Car owner with full, clean driving licence

OUTSIDE INTERESTS

Motorcycles, Music and Travel