Dr John Healey

Qualifications	B.Pharm. (Honours), London University 1964-1968, Specialised in pharmaceutics in final year PhD, Liverpool School of Pharmacy / ICI Pharmaceuticals, 1970-73 in Pharmaceutical Technology Member of the Royal Pharmaceutical Society of Great Britain (MRPharmS) Qualified Person under MAL 45 and Directive 75/319/EEC GCE 'A' levels in Chemistry, Physics, Biology, Mathematics, at Kings School, Macclesfield
Date of Birth	1945
Nationality	British
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Position at CWA

External Consultant on pharmaceuticals and their shipping

John Healey is a PhD pharmacist and Qualified Person (QP) with more than 30 years' experience gained in large multinational pharmaceutical companies, initially in new product research and development, and manufacturing, and then in QA with responsibilities that include batch review and formal release for worldwide markets. Self-employed for past 5 years in consultancy and advisory roles. Product experience particularly includes solid and liquid dosage forms, dermatologicals, sterile ophthalmic products and small volume parenterals, together with their stability issues and packaging needs. 13 of the previous 20 years at Merck Pharmaceuticals and SmithKline Beecham, followed by 4 years as QP at Amersham International/ GE Healthcare. Detailed knowledge of European GMP and regulatory requirements, and expertise on the Clinical Trials Directive (2001/20/EC). Experience of FDA CMC requirements including pre-approval inspections.

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Professional Experience

2003 – 2007 **Amersham International, now GE Healthcare Medical Diagnostics**
Quality Manager

Quality Manager, Operations, reporting to the UK Quality Manager as one of three QPs on the Company's main production site (1,000 staff) at Amersham. Responsible for setting and implementing quality standards throughout the site and for the review and release of product batches for markets worldwide, mainly radiopharmaceuticals as sterile parenterals, with about 70 product batches manufactured and released per week Quality Manager for the Physics Calibration Laboratory which is UKAS accredited and operates to ISO/ IEC 17025. Undertake quality audits throughout the site.

2002 - 2003 **Merck Pharmaceuticals, Hitchin**

Responsible for pharmaceutical development and clinical trial supplies at Merck Pharmaceuticals reporting to the site director Geoff Nicholson. The site at Hitchin was regarded as a centre of excellence and was one of 3 European sites supporting Merck research in French and German centres. However, a major reorganisation instigated by Merck Darmstadt resulted in closure of the R&D sites in UK and France late 2003.

2000 - 2002 **Interim Management Posts and Pharmaceutical Consultancy**

Interim management assignments with medium and large sized pharmaceutical companies especially on QA, QP and regulatory activities including:

- QA Manager for Faulding Pharmaceuticals Ltd, responsible for the UK/ EMEA region especially QP duties for batch assessment and release, pending recruitment of a permanent manager. The products were sterile parenterals for oncology and critical care, and the work included audits of suppliers and external manufacturers.
- Consultant and advisor to a large pharmaceutical development and clinical trials manufacturing dept in central Europe.
- Regulatory projects at GSK on Chemistry and Pharmacy dossiers, licence variations and pharmaceutical expert reports.

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1994 - 1999 **Stiefel International Laboratories, Maidenhead**
Head of Pharmacy

Head of Pharmacy at Stiefel R&D Laboratories responsible for a group of up to 36 staff in product development, clinical trials manufacture and supply, and the transfer of new products to the factory. Stiefel had about 2500 staff worldwide, working on prescription dermatologicals, but has since been acquired by and assimilated into GlaxoSmithKline and the Maidenhead facility has been closed.

1983 - 1994 **Pharmaceutical Development Dept., SmithKline Beecham, Welwyn Garden City**
New Product Development Manager

The Welwyn Garden site of 1,000 staff included the company's main European factory as well as the Pharmaceutical Development Department. Leading a team of up to 16, achieved the development and transfer into commercial manufacture of more than 20 new products (NCEs and life cycle developments) for worldwide markets, particularly for the UK, Europe and USA. Also responsible for introducing new processes into European and US plants, and for successful FDA pre-approval audits. R&D was subsequently centralised onto the Harlow site, then later moved to Stevenage, and the Welwyn Garden facilities were closed.

1981 - 1983 **HOECHST (UK) LTD, Basingstoke**

Head of a small pharmaceutical development group developing prescription and OTC products based on established actives, and especially sterile ophthalmic products. Manufacture was undertaken by external contractors, including Hoechst and Roussel factories.

1974 - 1981 **FISONS R&D Laboratories, Loughborough**
Section Head

Joined Fisons as Section Head of tableting, subsequently extended to include other dosage forms including sterile injectables and inhalation products.

1974 **BAYER AG, Leverkusen, Germany**
Industrial post-doctorate

Reported to Section Head Pharmacist, Tableting, in the Pharmaceutical Technology department. Employed on a fixed term post-doctorate.

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1968 - 1970 **BURROUGHS WELLCOME, Dartford, Kent**
Development Pharmacist

Worked mainly in the pharmaceutical development department on this large factory site. Employed under an SRC Science and Industry Award, prior to starting PhD.

Publications

Over 20 publications, mainly on pharmaceutical technology, drug delivery, and use of gamma scintigraphy in dosage form design. Inventor on a range of pharmaceutical patents.

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