Martyn Becker – *Curriculum vitae*

Details

Name:	Martyn BECKER
Address:	84 Cavalier Road, Old Basing, Hampshire RG24 7ET, UK
Telephone:	+44 7525 815012
Email:	martyn@martynbeckerassociates.com
Date of Birth:	13/02/53
Nationality:	British

Qualifications

- University of Wales, Cathays Park, CARDIFF, Wales, UK: July 1974: awarded Bachelor of Sciences with honours in Microbiology, 2nd class.
- Lead Assessor for pharmaceutically-orientated ISO9000 Quality Systems, 1991.
- Chartered Biologist and Member of the Royal Society of Biology (formerly Institute of Biology) status in 1992.

Summary

- Served within the pharmaceutical industry for forty-one years in Manufacturing and Quality (operational and managerial) positions, regarding many dosage form types (sterile, non-sterile solid, liquid, gel) and chemical/biological APIs.
- Five years with the UK MHRA as Manager and Senior Inspector, specializing in steriles, biologicals and blood collection centres/analytical laboratories. Also involved with the regulatory inspection of the manufacture/assembly of non-sterile solid, semi-solid and liquid dosage forms plus APIs, all on a global basis.
- Passionate about proactive system control, quality risk management and the 'right-first-time' philosophy.
- Believes that communication, consensus and execution are critically important in the achievement of world-class pharmaceutical quality standards.
- Has undertaken regulatory inspections/industry audits of research-based and generic manufacturers throughout Europe and the USA, South America, Japan, Turkey, South Africa, India, China, South Korea and Singapore. Has given many training courses within Europe, in the USA, South Africa, the Far East and Saudi Arabia. Most recent training has taken place with detailed classroom and on-site inspection training for a PIC/S accession country.

Career positions

Mar. 2008 to the present: Managing Director, Martyn Becker Associates Ltd.

Principal achievements:

- Set up MBA at the end of February 2008 to enable provision of pharmaceutical services based upon thirty-four years' industry and regulatory experience, primarily focused on aseptic and biological operations.
- Presented on the EU GMP Annex 1 update at the PDA 'Risk Assessment and Aseptic Processing' conference in Bethesda, Maryland in May 2008. Served on organising committees for the 2009 PDA/FDA (Washington) and PDA/EMEA (Berlin) conferences. Served on the organising team for the first PDA/PICS/ISPE conference on Quality Risk Management and aseptic processing in Geneva in November 2008.
- Provided assessment, pre-MHRA inspection preparation on a project management basis and training for the UK site of a global contract manufacturer. The inspection was successful.
- Undertook assessment, pre-licensing inspection preparation and training for a UK radiopharmacy site of a global manufacturer. The licence was granted.
- Worked with two global manufacturing companies to design and establish simple, working quality risk management systems to current regulatory expectation.
- Provided assessment, reporting and further recommendations concerning two refurbished aseptic processing facilities in the EU.
- Undertook site preparation and project management for a solid dosage form within Europe for a global contact manufacturer in advance of a FDA submission and inspection. The inspection was successful.
- Provided extensive assessment, pre-inspection preparation and training of a UK vaccines manufacturer in advance of UK and FDA inspection. The UK inspection was successful.
- Provided general GMP and specific aseptic training to inspectors from two regulatory agencies located in the Middle East.
- Undertaken numerous mock EU regulatory inspections and provided advice on facility construction and system implementation for vaccine and biological manufacturers in India, the EU and US.

- Worked with the World Bank regarding classroom and on-site training of regulatory inspectors within a PIC/S accession program.
- Provided troubleshooting and recommendations for the improvement of quality/feedback systems at a UK manufacturer.
- Currently providing expertise to, among others;
  - Two global biologics manufacturers regarding facility/water systems design and GMP assessment.
  - A global player in aseptic manufacturing regarding installation of an effective Quality Risk Management system.
  - A PDA (Parenteral Drug Association) task force regarding liaison with US FDA concerning GMP guidance harmonisation associated with the current FDA accession process into PIC/S;
  - Provision of subject matter expertise regarding the provision of expert reports concerning regulatory interpretation in the UK and USA.

Oct. 2007-Mar. 2008: Merck & Co. Inc., UK; Director Designate, MMD Divisional Auditing (Europe/Africa/Asia)

Principal achievements:

- Represented Merck Quality in the design of a new aseptic biologicals facility in the EU regulated to FDA and EU standards.
- Harmonised audit scheduling and planning process across Merck EMEA and Asia regions. Undertook assessment audits of regional auditors to recommend further training needs.
- Undertook auditor training at a global meeting of Merck auditors in the US.
- Successfully completed preparation of a Merck site situated in Europe concerning regulatory preparation in advance of FDA and EU inspections, and involved in preparation of three further sites that undertook regulatory inspection in 2008.
- Contributed a chapter on EU and US regulatory perspectives on aseptic processing to the second edition of a book on pharmaceutical microbiology for DHI/PDA, published in March 2008.
- Presented a perspective on 'Sterility – What Is An Acceptable Level?' at the PDA/EMEA Conference in Budapest, Hungary in February 2008.
- Served as part of the management board of the UK chapter of PDA.

Jan. 2002-Oct. 2007: Merck & Co. Inc., US/UK; Associate Director, MMD Sterile Quality Assurance

Principal achievements:

- Designed and directed the implementation of a global in-house standard for proactive control for aseptic manufacturing, initiated with an assignment in the US in 2002-3 involving the leadership of a number of multi-disciplinary teams.
- Represented Merck Quality on the facility design team for a new vaccine aseptic manufacturing facility in the USA, which came online in late 2008 and was successfully inspected by FDA and MHRA.
- Involved in the tracking of regulatory activities and the identification of current regulatory 'hot topics' via an in-house intra-divisional committee that provides direction, support and interpretation where necessary.
- Presented a corporate perspective concerning the 2001 FDA concept paper on aseptic processing at a FDA Advisory Committee meeting in Washington DC in 2002.
- Served as part of the Product Quality Research Institute team (PQRI) comprising industry, FDA and academia on recommendations for the update of the FDA draft aseptic guideline.
- Represent the Quality and Manufacturing/GMP groups of the European Federation of Pharmaceutical Industries and Associations (EFPIA) as sterile expert. Presented the EFPIA and PDA view of the Annex 1 review process to the EU Inspectors' Group in 2004. Following membership of the management committee, requested in September 2006 to serve as President of the PDA UK Chapter.

Jan. 2000-Dec. 2001: Merck Sharp & Dohme Ltd, UK; Senior Assessor, Merck Manufacturing Division Quality Assurance

Principal achievements:

- Published a book in 2000 called 'Understanding GMP – A Practical Guide' (DHI/PDA). Also contributed a chapter called 'European Regulatory Perspective' to a book on pharmaceutical microbiology, published by DHI/PDA in July 2001, the second edition of which was published in 2008.
- Introduction of risk-based assessments and audits of in-house Quality Assurance systems, focusing on sterile manufacturing and solid dosage forms.
- Carried out training of corporate Quality auditors on audit technique, with additional focus on sterile manufacturing.
- Developed in-house input into industry support organisations such as EFPIA.

Sep. 1998-Dec. 1999: Medicines & Healthcare products Regulatory Agency (formerly Medicines Control Agency), Manager and Senior Inspector, Southern Region, UK

Principal achievements:

- Managed the Southern Regional Office, directed a team of Medicines Inspectors and assessed inspector competency.
- Inspected sterile, biological, blood product and other dosage form manufacturers in the UK and internationally. Provided technical support and input on sterile and biological manufacturing to the MHRA management group.
- Wrote, reviewed and commented upon updates within the EU GMP guide, specifically the sterile products Annex 1 in 1996. Also reviewed and commented upon the current Qualified Persons' Code of Practice in the UK and have lectured internationally on this subject.
- Formed part of the European Medicines Agency's inspection team that assessed the Canadian inspection system in Canada as part of the Mutual Recognition Agreement that is currently in place.

May 1996-Sep. 1998: MHRA (formerly MCA), Southern Region, UK; Senior Medicines Inspector, Steriles/Biologicals/Blood Products

Principal achievements:

- Global regulatory inspections focusing on sterile, biological and blood products, plus:
- Represented MCA at UK Governmental liaison meetings on biological products.
- Promoted to Regional Manager.

Apr. 1995-May 1996: MHRA (formerly MCA), Southern Region, UK; Medicines Inspector

Principal achievements:

- Regulatory inspections of pharmaceutical manufacturers (all dosage forms), assemblers and wholesalers, plus:
- Performed regulatory inspections on behalf of the European Medicines Agency.
- Promoted to Senior Inspector.

Aug. 1992-April 1995: SmithKline Beecham Pharmaceuticals, UK; Regulatory Compliance Manager

Principal achievements:

- Expanded the operation, scope and focus of the internal/external audit function to include guest audit at corporate level international audits.
- Served as Person Responsible for Quality on the site Manufacturing Authorisation in the absence of the Head of site Quality.
- Served as site liaison with regulatory agencies regarding inspections and filings.
- Developed control systems to assure the presence of current regulatory information to facilitate product release and for homogeneity of site procedures.

Apr. 1991-Jul.1992: SmithKline Beecham Pharmaceuticals, UK; Regulatory Compliance Officer, Quality Assurance

Principal duties:

- Conducted routine cGMP audits at site and UK level.
- Undertook cGMP training for site employees.

Key achievement:

- Designed, set up and implemented a site-wide Good Manufacturing Practice Training initiative in 1992.

Apr. 1979-Mar. 1991: Beecham/SmithKline Beecham Pharmaceuticals, UK; Microbiological Section Head, Bencard Allergy Unit

Principal duties:

- Managed the sterile production of a range of microbiological raw materials for use in allergy desensitising vaccines.

Key achievement:

- Designed the microbiological section and assisted in the overall facility design, qualification and process validation of a new facility housing the Allergy Unit in 1983/4.

Jun. 1977-Mar. 1979: Beecham Pharmaceuticals, UK; Microbiologist, Bencard Allergy Unit

Principal duties:

- Produced a range of sterile microbiological starting materials for desensitising vaccine production.

Nov. 1974-Jun. 1977: Beecham Pharmaceuticals, UK; Scientific Officer, Microbiological Assay Services Unit

Principal duties:

- Routine bio-assay in support of stability studies

Additional information

- Served as sub-team leader in 2005 for provision of an EFPIA position paper on the Quality aspects of a Clinical Trial dossier, and as team member of the EFPIA Clinical Trial Directive Implementation task force.
- Member of the Aseptic Processing Task Force within PhRMA (the US Pharmaceutical Research and Manufacturing Association) from 2002 to 2004, resulting in revision of the FDA aseptic processing guidance, published in 2004.
- Member of the Pharmaceutical Manufacturing Committee for the Association of the British Pharmaceutical Industry (ABPI) from 1990 to 1995 and of the Institute of Quality Assurance's Pharmaceutical Quality Group from 1991 to 1995.
- Invited by FDA in 2007 to provide a training seminar for investigators on quality systems topics at FDA headquarters in Rockville MD.
- Eligible for Qualified Person status via the UK transitional arrangements and also completed a formal course of study enabling status of Qualified Person under the permanent provisions in 1994. This was required as part of my application for employment with MHRA as a Medicines Inspector.