



## CURRICULUM VITAE

# Brij Patel

**BPharm, PhD**  
**Senior Consultant, GxP Assure**



### Recognised Areas of Expertise:

- Over 12 years of experience as a Regulatory and CMC Consultant across the EU, UK, and US
- 8 years as a CMC assessor with the MHRA, also serving as an expert to the EMA, Biologicals, for example:
  - Vaccines: pandemic/seasonal influenza vaccines (H1N1v/H5N1, trivalent/quadrivalent), polysaccharide vaccines (meningococcal, pneumococcal), paediatric vaccines, BCG vaccine, Jap encephalitis vaccine, malaria vaccine, immunotherapeutics (oncology vaccines);
  - Recombinant proteins: filgrastim, PDGF (becaplermin), somatropin, insulin, etanercept, monoclonal antibodies (e.g. trastuzumab), recombinant clotting factors
  - ATMPs – MHRA/CHMP scientific advice procedures
  - Blood products: plasma-derived products (e.g. C1-esterase inhibitor, clotting factors, IgG)
  - Other Biols: Heparin, oligodeoxynucleotides, pancreatin.
- Small molecules (Chemicals), for example:
  - Fermentation products, modified release products, various dosage forms (oral, transdermal, nasal, parenterals), bioequivalence studies. Experience in products across a range of therapeutic areas.
- Extensive regulatory and CMC expertise across biologicals (including biotech proteins, vaccines, and ATMPs), biosimilars, and small-molecule products.
- Served as Lead EU Assessor for numerous new drug and biologics applications, abridged submissions, clinical trial applications, and post-approval lifecycle procedures.
- Contributed as an author to multiple EMA/CHMP regulatory guidelines.
- Qualified Pharmacist holding a PhD focused on vaccines and drug-delivery technologies.



### **Current Employment:**

- Independent Consultant working on behalf of GxPAssure Limited
- Director of independent consultancy providing services for multiple pharmaceutical companies

### **Career History:**

- **2013 – current: Independent Consultant, London**
  - Regulatory and technical assistance (biopharmaceuticals and small molecules):
  - Product development and regulatory consultant to a large number of (bio)pharmaceutical companies.
  - Provision of European CMC/Module 3 regulatory requirements for MAA and CTA
  - Consultant for number of US ANDAs, and lead presenter at PDMs, FDA clarification meetings, Enhanced Mid-Cycle review meetings
  - Regulatory strategy and classification (generics, biologics, borderline products, drug-device combos);
  - Regulatory agency interactions (meetings, scientific advice, submissions and responding to questions);
  - Independent expert advice on failed/defective batches and identification of key regulatory issues and solutions

- **2005-2013: Medicines & Healthcare Products Regulatory Agency (MHRA), UK**

#### Technical

- Over 8 years as reviewer for CMC dossiers for initial applications and post-approval variations (National, MR/DCP, Centralised) and CHMP/MHRA scientific advice, including:
  - Biologicals, for example:
    - Vaccines;
    - Recombinant proteins;
    - ATMPs;
    - Blood products;
  - Small molecules (Chemicals)
  - Defending decisions at MHRA expert committees (e.g. CHM) and EMA (e.g. BWP, QWP, CHMP)
  - Complex formulations (innovator/generic liposomals, nanoparticles);
  - Drug-Device combinations
  - Assessment of failed/defective batches
  - Clinical Trials Application assessment.

#### Managerial:

- Since 2009 – 2013 additional duties as MHRA Deputy Manager:
  - Operational management of the Biologicals Unit (~25 people multidisciplinary team);
  - Regulatory pathway advice (biosimilars, generics, device combinations, ATMP);
  - Approval of assessment reports/recommendations for Expert committees and external release;
  - Managing official unit correspondence to the Government, EMA, Other regulators, Media and the Public;
  - Visiting and hosting International Regulators to discuss issues relating to Biological products.
  - Author for a number of CHMP guidelines (e.g. liposomal generics, influenza vaccines, polymer coated iron nanoparticles) and contributed to many others in capacity of MHRA/EMA assessor and manager
  - Lead MHRA quality assessor for development of a UK compassionate-use scheme (Earlier Access to Medicines);
  - Invited speaker at a number of International conferences including (see list at end)
- **2001 – 2004: Self-Employed Locum Community Pharmacist**
  - **Pre-registration pharmacist (Community Pharmacy).**

#### Education:

- 2001-2004 PhD: Polymerised Liposomes as Intranasal Vaccine Adjuvants, School of Pharmacy, London.
- 1998-1999 Pharmacy Body Professional Registration examination.
- 1998-2000 Pharmacy degree (BPharm), School of Pharmacy, University of London.

#### Conference Presentations, Workshops, Papers:

- Expert Review of Vaccines, 6(5), 2007 (“New adjuvants: EU regulatory developments”) – publication
- EUFEPS workshop: Opportunities and Challenges in Vaccine Delivery, Geneva, 2008. Invited speaker (“Vaccine Delivery: Regulatory perspective”)
- Invited expert to NIAID (US National Institute of Allergy and Infectious Diseases) on suitable adjuvant candidates (2008);
- Immunopotentiators in Modern Vaccines (IMV), Montego Bay, 2009. Invited speaker (“Regulatory expectations regarding safety of new adjuvants”)

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- Vaccine forum, Geneva, 2009. Invited speaker – Joint presentation (“New adjuvants and EU regulatory developments”)
- UK Controlled Release Society, London, 2009. Invited speaker (“Drug delivery: From laboratory to licensure”)
- India Bio, Bangalore, 2010, Invited speaker (“Regulator’s perspective for Biologicals and Biotechnology products”)
- Modern Vaccine Adjuvant Formulation (MVAf), Cannes, 2010. Invited speaker (“Regulatory issues relating to Vaccine and Adjuvant formulation”)
- Biosimilars India, Mumbai, 2011, Invited speaker (“MHRA’s perspective on Biosimilars”) and panel session (Biobetters);
- Modern Vaccines, Adjuvants and Delivery Systems (MVAD), Copenhagen 2012. Invited speaker (“Challenges in characterisation and control of novel vaccines”)
- NIBSC-WHO-Vaccine manufacturers biannual Influenza meeting, Potters Bar, 2012, 2013. Invited speaker/participant (Seasonal trivalent and tetravalent influenza vaccines)
- Regulatory Seminar for NIBSC staff, London, 2012. Invited speaker (“Vaccines: Regulatory pathway, monitoring safety and dealing with emerging issues”)
- Pharmacovigilance, London, 2013. Invited speaker (“Regulatory pathway, monitoring safety and dealing with emerging issues”)
- Biosimilar Drug Development World, London, 2013. Invited panel member (“Global regulatory – is harmonised international development in sight”)
- Pathways to commercial nanomedicines; Stevenage, 2013. Invited expert for roundtable discussion
- Getting early stage products into development and manufacture; London, 2013. Invited speaker (“Regulatory route and challenges for new vaccine technologies”);
- Creating a step-change in Drug Delivery Systems, Nottingham BioCity, 2013. Invited speaker (“Drug Delivery - regulatory perspective and case studies”);
- GMP review, 12(1), April 2013 (“Regulatory experience with QbD submissions for biological products”) – publication
- Modern Vaccine Adjuvant Formulation (MVAf), Lausanne, 2013. Invited speaker (“Anticipating the regulator – vaccine CMC”);
- Pre-filled Syringes Congregation, London, 2013, Conference Co-Chair and panel session member:
  - Developing regulatory framework in advanced and developing markets
  - Challenges and Opportunities.
- Bioproduction, Dublin, 2013. Invited speaker (“Getting your QbD programme past the regulators”);
- Mucosal Vaccines, Adjuvants and Delivery (MUCOVAD), Copenhagen, 2013. Invited speaker (“Regulatory and CMC challenges for mucosal vaccines”);
- Informa training course - to Industry and Regulators, London, 2013, 2014, 2014 (“Comparability for Biologics”);

- Global Pharma Regulatory Summit, 2014, Mumbai. Invited speaker and Chair (“QbD: Regulatory update”);
- International Symposium on Polymer Therapeutics, Valencia, 2014. Invited speaker (“Manufacturing and regulatory challenges for nanomedicines/polymer therapeutics”)
- PAT and QbD Summit, London, 2014. Invited speaker (“QbD: Regulatory Update”)
- WHO Workshop on the regulatory requirements for the preclinical/non-clinical and clinical evaluation of influenza vaccines (human, live attenuated and inactivated), 2014, Bangkok. Invited expert for preparation and delivery of workshop training to National Regulatory Reviewers and Industry.
- Biosimilar Insulin Regulatory Profile, April 2017, The ACCISS Study, Health Action International
- Frontiers in Immunology, Oct 2017, “TBVAC 2020: Advancing TB vaccines from discovery to clinical development”
- Nanotherapeutics for antibiotic resistant emerging bacterial pathogens, Madrid, 2017 (“Regulatory aspects on quality requirements for use of nanocarriers as medicinal products”)
- Biologics Workshop, Knowledge sharing presentations to Middle-East Regulatory Agency, 2017
- TBVAC 2020: Portfolio management and prioritisation, Les Diablerets, 2018
- TBVAC 2020: Portfolio assessment, Les Diablerets, 2019