CURRICULUM VITAE

Patrick John Crowley

Date of Birth:	June 12th 1942
Place of Birth:	Republic of Ireland
Nationality:	Irish
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Education

1954 – 1959	De La Salle High School, Skibbereen, Co. Cork, Ireland. • Intermediate Certificate (Hons) • Leaving Certificate (Hons)
1962 – 1965	i) University College Cork. ii) College of Pharmacy, Dublin. • Diploma in Pharmacy; 1st Class Hons: Gold Medallist.

Current Positions Founder and Owner: Callum Pharmaceutical Consultancy; Philadelphia Pa USA (www.callumconsultancy.com). Visiting Professor at The School of Pharmacy: King's College; London; UK

Previous Employment History and Product Involvements

1. Various appointments with GlaxoSmithKline, SmithKline Beecham, Beecham Pharmaceuticals and Wyeth:

2001 – 2008	Vice-President in Pharmaceutical Development, GlaxoSmithKline (US). Lead groups that developed product forms for Augmentin ES (antibacterial) Suspension and Coreg CR Capsules (Cardiovascular Agent). Lead a "Quality by Design" Team responsible for programs and studies on design, manufacture and control of a monoclonal antibody (mepolizumab), an IL5 antagonist for severe asthma now available in the US and Europe as Nucala.
1998 – 2001	Group Director; SmithKlineBeecham Harlow (UK) and Bristol, Tennessee (US). Lead group that developed the products, Augmentin XR Tablet and Augmentin ES Suspension (antibacterials).
Mar-Dec 1997	Group Director, Pharmaceutical Development (Harlow, UK). Lead group that developed the dosage form for the novel Quinolone antibacterial gemifloxacin (Factive) and the dosage form design program that lead to the approval in 2018 of the antimalarial, tafenoquine as a single-dose treatment for recurring ("relapsing") malaria attributable to extended *Plasmodium.vivax* dormancy in the liver (program under the aegis under the aegis of the Medicines for Malaria Venture)

		The medication is hailed as a major and radical breakthrough/cure for *P.vivax* malaria.
	1993 – 1997	Director Pharmaceutical Development (Worthing, UK) Managed department that developed (commercial) product forms for famciclovir (oral antiviral), penciclovir topical and parenteral (antivirals) and topical mupirocin Bactroban Cream (antibacterial).
	1991 – 1993	Manager, Pharmaceutical Development group; SmithKline Beecham; Welwyn Garden City; UK. Lead group that developed cimetidine OTC Tablet (Tagamet).
	1984 – 1991	Manager, Pharmaceutical Development Department; Beecham Pharmaceuticals; (Great Burgh), Epsom, Surrey, UK. The department developed product forms for Paxil/Seroxat (paroxetine anti depressant), Kytril (granisetron anti emetic) and Eminase (thrombolytic) as well as a range of anti allergy vaccines.
	1982 – 1984	Unit Head; Great Burgh. Unit developed nabumetone (anti inflammatory) dosage forms.
	1979 – 1982	Unit Head; Worthing; UK Unit developed product forms for an improved-tasting flucloxacillin (Floxapen) Oral Suspension and mupirocin (Bactroban) Ointment (topical antibiotic).
	1972 – 1979	Section Head (Worthing). Lead Teams that developed product forms for the antibacterials talampicillin (Talpen), amoxicillin-clavulanate oral and IV (Augmentin) and ticarcillin-clavulanate parenteral (Timentin).
	1971 – 1972	Development Pharmacist Beecham Pharmaceuticals, Worthing. Propounded and initiated a program that lead to a product and process for the manufacture of the injectable antibacterial, amoxicillin (Amoxil).
2.	1966 – 1971	Development Pharmacist; Wyeth, Maidenhead, Berks, UK
3.	1959 – 1962	Trainee Community Pharmacist: PJ. Dennehy & Co, Skibbereen, Co. Cork, Ireland.

Achievements and present activities:

- I played significant technical and management roles in the development to commercialisation of over 20 novel medicinal products throughout my career in the Pharmaceutical Industry. Active ingredients in such products included novel chemical entities, fermentation products, semi synthetics and two biopharmaceuticals

- Since retiring from GlaxoSmithKline in 2008 I have maintained an interest in many areas of pharmaceutical sciences and have presented and published in the area (see Presentations/Publications list at the end of document).

- Other activities include

o I act as a consultant for various multinational, mid-size and startup healthcare organisations in "trouble-shooting technical problems", product registrations (filings), dosage form development and patent litigation.

o I am a Visiting Professor at The School of Pharmacy, Kings College, University of London, providing input in the following areas

- teaching classes (to Masters students) on Biopharmaceuticals, Immunotherapeutic Agents and Vaccines.
- Providing suggestions (via Professor L G Martini) on Projects for Masters students
- Contributed to a PhD program related to Drug Delivery to the brain.
- Member of a team that developed an online teaching module for Biopharmaceuticals for Colleges throughout the European Union ("PHAR-IN" program). Prepared the module for biopharmaceutical dosage form design, and manufacture.
- Worked with Professor LG Martini in discussions with other King's College academic professionals to explore possibilities for collaborative work on drug delivery to the brain (Professor C Ballard and Dr J Maher; Guys Hospital).

Publications/Presentations

See below.

Professional Affiliations and Activities

- Visiting Professor: Institute of Pharmaceutical Sciences: King's College, University of London, UK.
- Fellow of the Royal Pharmaceutical Society of Great Britain.
- Lecturer on Dosage Form Design and Manufacture at Training courses for M.Sc in Regulatory Affairs (organised by The European Organization of Professional Regulatory Affairs (TOPRA).

Patents

- International Patent WO2015/155544 A1 (2015): Delivery of Non-Steroidal Agents to the Brain via the Nasal Tract to Treat Neurological Disorders (co-inventor with LG Martini, K Al-Jamal, LG Martini, D Templeton).
- US Patents 10/997836 and US 2005/01756595 A1 (co-inventor). "Carvedilol Controlled Release Compositions". Patents pending in other countries.
- US Patent WO 96/01109 (1995) Improved Tolerance Clavulanate Compositions
- US Patent 4 898 580 (1990) Syringe for a Liquid Pharmaceutical
- US Patent 4 441 609 (1984) Pharmaceutical Compositions
- UK Patent 2 005 538B (1982) Pharmaceutical Compositions
- US Patent 4 301 149 (1981) Clavulanate/Trihydrate Formulations

Publications

- Preservation of Pharmaceutical Dosage Forms: Chapter 38 in Block's Disinfection, Sterilization, and Preservation, 6th edition. Co-author with DP Elder (in Press).
- Fixed Dose Combinations (Book Chapter): co-author with LG Martini, SM Maglennon, D Templeton (in Press).
- Quality by Design for Generic Products: Opportunities and Challenges: (co-author with S McCallion): European Pharmaceutical Review:
  - Part One: Issue 6 2016: Part 2 Issue 1: 2017.
- White Paper: Pharmaceutical Quality Metrics (Jan 2016): Xavier Health, Xavier University, Cincinnati/PWC Consultants (co-author/contributor).
- Redesigning Drugs to Enhance Performance (Co-author with L.G.Martini); Pharma Focus Asia; Issue 23 (2015), p 20-27.
- Optimizing Drug Delivery: The Challenges and Opportunities: Co-author with Prof LG Martini: June 2015 ONdrug delivery (2015) **59** 4-11.
- A European Competence Framework for Industrial Pharmacy Practice in Biotechnology Co-author with various Academic/Industrial Scientists: Pharmacy (2015) 3, 101-128; doi:10.3390/pharmacy3030101.
- Controlling Release from Dosage Forms: The Future (co-author with Professor LG Martini and Dr S Ibrihim); American Pharmaceutical Review; June 2012.
- Antimicrobial Preservatives (co-author with Dr David P Elder): January 2012
  Part I: Choosing a Preservative System.
http://www.americanpharmaceuticalreview.com/Specialty/Formulation_Development/Featured-Articles/38885-Antimicrobial-Preservatives-Part-One-Choosing-a-Preservative/
  Part II: Choosing a Preservative;
http://www.americanpharmaceuticalreview.com/Specialty/Formulation_Development/Featured-Articles/38885-Antimicrobial-Preservatives-Part-Two-Choosing-a-Preservative/
  Part III : Challenges Facing Preservative Systems;
http://www.americanpharmaceuticalreview.com/Specialty/Formulation_Development/Featured-Articles/38874-Antimicrobial-Preservatives-Part-Three-Challenges-Facing-Preservative-Systems/
- Excipients: Why We Need to Know them Better (with LG Martini): World Pharmaceutical Frontiers, Sept 2011.
- Excipients in Parenteral Products. Chapter126 (with LG Martini). Encyclopaedia of Pharmaceutical Technology: Marcel Dekker New York. 2013.
- Co-Editor with Professor Clive Wilson of Textbook "Dosage Forms for Oral Controlled Release": Controlled Release Society; Springer Publications, 2011; http://dx.doi.org/10.1007/978-1-4614-1004-1.
- Controlling Drug Release in Oral Product Development Programs: An Industrial Perspective (with LG Martini) Chapter 3 in "Dosage Forms for Oral Controlled Release" (Springer Publications, 2011; http://dx.doi.org/10.1007/978-1-4614-1004-1.
- Supply Chain Management in Development Programs: in Chapter 13: Supply Chain Management in the Drug Industry: co-Author with H Rees; JWBS050-Rees; 2010 ISBN-13: 978-0470555170. John Wiley and Sons.
- Effect of Excipients on the Stability of Medicinal Products (with LG.Martini) Chimica Oggi (2010) 28 (5) VII-XI.
- Op-Ed; "Stability Programs need to be Re-invented": GMP Review 8 21-22 (2010)
- Redesigning Drugs to Enhance Performance (with LG.Martini); Pharma Focus Asia; Issue 4 (2007), p 24-30.

- Influence of Ethanol on Release from Hypromellose Matrices (Int.J.Pharmaceutics (2007) ***332*** 31-37. (with LG.Martini and collaborators at The School of Pharmacy; John Moores University, Liverpool, UK.
- Low Dose Lipid Formulations: Effects on Gastric Emptying and Biliary Secretion: Pharm Research (2007) **24** (11) 2084-2096. Co-author with colleagues at GSK, U of Strathclyde, UK and Monash U, Melbourne Australia.
- The Influence of Ethanol on Aspirin release for Hypromellose Matrix Tablets (Poster) British Pharmaceutical Conference: Sept 2006 (co-author with MJ Roberts, M Cespi, JL Ford, AM Dyas (all at J Moores Univ Liverpool UK), and LG Martini.
- Formulation Design: New Drugs from Old (with LG Martini): Drug Discovery Today; Therapeutic Strategies (2004) 1 (4) 537-541.
- Physicochemical Approaches to Enhancing Drug Absorption (with LG Martini*):* Pharmaceutical Technologies Europe (2004) **16** (9) 18-2**7.**
- Drug-Excipient Interactions: (Review): Pharm Technology Europe, 2001 13 (3) 26-34. (with LG Martini).
- Enhancing Oral Absorption in Animals: (Review): Current Opinion in Drug Discovery and Development 2001 4 (1) 973-80. (with LG Martini).
- Excipients in Pharmaceutical Products (Chapter): Encyclopoedia of Pharmaceutical Technology: Marcel Dekker New York (2002) 1151-1163 (with LG Martini).
- Solubility Parameter & Oral Absorption: Eur.J.Pharmaceutics & Biopharmaceutics. 1999 48 (3) 259-263. (with Martini.L.G, Avontuur P, George A, Willson R).
- Excipients as Stabilisers. (Review). Pharmaceutical Science and Technology Today; 1999 2 (6) 237-243.
- International Stability Testing (Review). Pharmaceutical Science and Technology Today 1999 2 (6) 227-228.
- Compaction Induced Solid State Reactivity: (Poster) T.D. Sokoloski, K.C. Campbell, P.J. Crowley, M.J. Greenway, C.E. Valder, M. Pudipeddi, and F.X. Muller. AAPS 11th Annual Meeting; 1996. Abstract/PDD 7140, Pharm. Res. 13, S-267, 1996.
- Using Microcalorimetry to Optimize Bioavailability: (Poster) Sokoloski.T, Ostovic.J, Muller.F, Oh.CK, Crowley.P.J, and Baldoni.J.M. AAPS, San Francisco, November 1998 and Pharm. Res. 1, S-490-491.
- A Time-Temperature Indicator Label for use with Thermally Sensitive Products: (Poster): FIP Congress of Pharm Sciences, Munich, Sept 1989.
- The Effect of Temperature and Relative Humidity on the Moisture Vapour Transmission Rates of Blister Materials: (Poster): FIP, Amsterdam, Sept 1987.
- Bacteriological Aspects of Talampicillin (co-author): Brit.J.Clin. Pract (1975) 29 (10) P268-9.

Oral Presentations

- Preservation of Pharmaceutical Products: Education Seminar: New England Chapter – Society of Cosmetic Chemists. Cosmetic Product Preservation. Today's Challenges for Tomorrow's Needs: Worcester Mass, USA, Oct 2018.
- Drug Delivery 2017: The Path Forward: CMC and Quality Considerations: Controlled Release Society Annual Meeting; Boston Mass, July 2017 (Catalent pre-meeting workshop).
- Presentations (3) on Vaccines (Anti Infectives and Immunotherpaeutic Agents), Biopharmaceuticals and CombinationProducts at Pharmaconex Technology Conference; Cairo, Egypt; April 2017.
- Training Programme on Dosage Form Design and Evaluation; The Ministry of Health, Lagos, Nigeria: April 2016.

- Defining and Attaining Target Performance Profiles for Dosage Form Design: SMI Conference, London March 2014
- Quality by Design: Experiences and Perspectives: Drug Delivery and Formulation Asia Summit; Shanghai, China, Oct 2012.
- Process Analytical Technologies in Quality by Design: Quality by Design 2012 Conference, Mumbai, India April 2012.
- Quality by Design, The Science of Stability Testing, Drug Excipient Interactions (3 presentations); International Conference of Pharmaceutical Technologies, Future University of Egypt, Cairo, Egypt; Feb 2012.
- Challenges in Formulating Pediatric Medicines: Formulation Summit: Los Vegas (US) Feb 2012.
- Optimizing Product Life Cycle by Formulation**:** Drug Delivery and Formulation Asia Summit; Shanghai, China, Dec 2011.
- Supply Chain Management in Clinical Trials: GoC Conference; Xavier College, Cincinnati; Oct 2011.
- Formulation Changes in Late Development: Controlled Release Society Meeting: Miami, January 2011.
- Platform Technologies in Oral Drug Delivery: Controlled Release Society Annual Meeting, Portland Oregon; USA; July 2010.
- QbD in Dosage Form Design and Manufacture: Royal Saudi Pharmaceutical Society Conference: Riyadh, Saudi Arabia; April 2010.
- Dosing Strategies for the Elderly: Controlled Release Society Workshop; New York: July 2008.
- Western and Chinese Medicine: Best of Both Worlds: China 2008 Pharmaceutical Summit: Shanghai; China; April 2008.
- Reformulating Medicines to Improve Performance: Evolution Summit: Las Vegas, USA March 2008.
- Life Cycle Management of Biopharmaceuticals: Keynote Speaker; Bio-Forum 2007: Shanghai: China: July 2007.
- New Medicines from Existing Drugs: 10th Healthcare Industry Forum: Beijing, China Oct 2006.
- New Medicines from Current Drugs: Pharmaforum –CPHI: Madrid 2005.
- Formulation for Paediatrics: British Pharmaceutical Conference: Sept 2005.
- Drug-Excipient Interactions: 3rd International Symposium on Excipients: Sept 2003; Stockholm; Sweden.
- Drug and Product Stability: Sino-American Pharmaceutical Association Meeting: Philadelphia, USA; Oct 2002.
- Accelerating Drugs to the Market. The Pharmaceutical Development Perspective: IBC International Conference, London, December 1995/November 1996.
- Formulation of Macromolecules for International Registration; PhMRA Meeting Orlando, Florida, May 1990
- The Role of Pharmaceutical Development in International Drug Development: European Society of Regulatory Affairs, Paris, March 1989.
- Virtual Temperature for Storage in a Tropical Environment: FIP Congress of Pharm Sciences, Amsterdam, September 1987.
- The Activity of Ticarcillin in the Presence of Anti-Cancer Agents: *Chemotherapia* 1983 2 P464-7. Mediterranean Congress of Antimicrobial Therapy, Dubrovnik, Yugoslavia; Sept 1982.
- Dosage Form Development: Conference on Drug Quality, Kuwait, November 1982.
- Pharmaceutical Development and Quality Control: Pharmaceutical Sciences Congress, University of Damascus, Syria, May 1981.