

Curriculum Vitae

Dr LUCIO FUMI, MD



PROFILE

- **European pharmaceutical physician, with Medical Registration in Italy and the United Kingdom**
- **Over 30 years of industrial experience in major international healthcare companies in Italy, Germany, Slovenia, Belgium, the Netherlands and the UK**
- **Experience in clinical development and medical affairs in both large corporations and start-ups, in ethical pharmaceuticals, medical devices, biotechnology, medical food (FSMP), healthcare products companies**
- **Ability to work both independently as a consultant, and in corporate positions, managing professional teams of all sizes**
- **Track record in building effective, transnational medical and regulatory teams across Europe / EMEA**
- **Familiarity with regulatory and reimbursement authorities, industry associations, health economics centres of excellence**
- **Experience in a broad range of therapeutic areas, to include:**
 - interventional oncology (chemo-embolisation, thermal ablation, Selective Internal Radio Therapy – SIRT)
 - oncology: surgical (colorectal and pelvic floor surgery, melanoma); medical (TNF-soluble receptors); loco-regional therapies (ILP, HIPEC);
 - clinical nutrition (malnutrition, enteral and parenteral nutrition, nutraceuticals, pharmaconutrients);
 - gastroenterology, manipulation of microbiota through prebiotics and probiotics;
 - infectious disease and antibiotic treatment;
 - extracorporeal circulation treatments in intensive care;
 - volume replacement in shock (artificial plasma substitutes, haemodilution, autotransfusion);
 - haemapheresis, blood transfusion and blood components

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CAREER HISTORY

WYFOLD MEDICAL, a medical consultancy agency

1998 – present

Founder and Chief Executive Officer, with interim management and consultancy activity, working with independent professional associates across Europe, in the areas of clinical research, medical affairs, regulatory affairs, medical devices reimbursement, market research, strategic marketing and early development of inventions. Clients include Amgen, Baxter, Dideco, Fresenius, Nestlé Clinical Nutrition, Pfizer Consumer Healthcare, and a number of start-ups (full list on the website www.wyfoldmedical.org). Based in Howbery Business Park, Oxford, UK

Corporate, interim and board positions:

Director of Medical Affairs, Piramal Critical Care (2019-present)

Director of Medical Affairs for the full portfolio of the company, including anaesthetics, opioids and pain management products, plasma expanders and other critical care intravenous or intrathecal products. Global responsibility across the three hubs of the company, in Bethlehem (PA), Mumbai (India) and London Heathrow (UK).

Medical Director, Tensive (2018-present)

Leading the clinical development of an innovative biocompatible material for the intra-operative filling of surgical vacuum created by lumpectomy or quadrantectomy in breast surgery. Based in Milan, Italy.

Chairman of the Board, BetaGlue Technologies (2016-2018)

Leading the clinical development of an innovative medical device for locoregional therapies in oncology. The device was designed for the intratumoral interstitial injection of a gel matrix containing beta-emitting isotopes. BetaGlue technologies (formerly Seventeen) is a start-up financed by two major Italian VC firms. Based in Milan, Italy.

Chief Medical Officer, Clasado Biosciences (2016)

Upgrade to drug status of second generation GOS prebiotics with the FDA; Investigational New Drug Application for the indication of Travellers' Diarrhoea and set up of pivotal clinical trial. Based in St Helier, Jersey and Reading, UK.

Head, Medical Affairs, Interventional Oncology, Terumo Europe (2015-16)

Set-up of the Medical Affairs and Clinical Development team and activity for the new Division of Interventional Oncology for EMEA (loco-regional treatment of cancer: vascular access, microwave ablation, chemo-embolisation, radio-embolisation). Based in Leuven, Belgium.

Director, Liver Cancer, Interventional Oncology, BTG (2013-15)

Medical Marketing, Market Access and KOL management; advisory role to General Management for the Interventional Oncology Division / loco-regional treatment of cancer (chemo-embolisation, radio-embolisation). Based in Camberley, UK.

International Medical Director, Interventional Oncology, Biocompatibles (2012-13)

International Medical Director (ex-US) for Chemo-embolisation products, and integration of the radio-embolisation business (TheraSphere) acquired from Nordion. Based in Farnham, UK. Biocompatibles later became fully integrated into BTG.

Chief Medical Officer, Clasado Biosciences (2011-13)

Medical affairs and medical marketing activity for the development of second generation GOS prebiotics, specifically aimed at Irritable Bowel Syndrome, Travellers Diarrhoea, and prevention of *Clostridium Difficile* infection in hospital and the community. Based in Sliema, Malta, and Milton Keynes, UK.

Medical Director, Astellas Pharma, South East Europe (2011)

Set up of the Medical and Regulatory Affairs department in the new affiliate, including Slovenia, Croatia, Bosnia, Romania and Bulgaria, in all the company therapeutic areas. Based in Ljubljana, Slovenia.

Chief Medical Officer, Biopheresis (2008-11)

Set up and leadership of a programme of clinical development of Oncosorb, an Advanced Therapies cartridge for the treatment in extracorporeal circulation of advanced forms of cancer, through immuno-adsorption of specific cytokines receptors (soluble TNF- α receptors). The cartridge was included in the circuitry of a Fresenius machine for therapeutic plasmapheresis. Based in Heidelberg, Germany.

Chief Medical Officer, Rand Biotech (2009-10)

Medical marketing activity for the development of innovative advanced procedures for the treatment of peritoneal carcinomatosis (Hyperthermic Intra Peritoneal Chemotherapy – HIPEC) and peripheral sarcomas and melanomas (Isolated Limb Perfusion - ILP) with high-volume fluid management machines. Based in Mirandola, Italy.

Medical Director, Nutricia, a Numico affiliate (2006-08)

Based in Trowbridge, UK, and Amsterdam, The Netherlands. Member of the UK and Ireland Leadership Team. Leading a team of 20 scientists and dieticians. Chairman of the Professional Relations Working Group of the Medical Nutrition Executive of the Industry Association. Leader of European task force to drive regulatory changes across the industry and reimbursement of clinical nutrition.

Medical Director EMEA, Hospira Healthcare, a spin-off from Abbott (2004-06)

Based at the EMEA headquarters in Hoofddorp, the Netherlands; member of the EMEA management team. Set up of medical affairs services for the new company (hospital products, including a vast portfolio of proprietary and generic IV drugs and medical devices for surgery, anaesthesia and intensive care) in Europe, Middle East & Africa. These included medical information, medical communication, product vigilance, clinical research and development, product launches, set-up of networks of Key Opinion Leaders.

Medical Director, ConvaTec Europe, a Bristol-Myers Squibb company (1995-98)

Based at the European headquarters in Ickenham, UK. In charge of medical affairs and clinical research. Reporting to the Vice President of ConvaTec, Chronic Care, Europe. Leading a team of 8 Medical Associates located in the major European countries. Medical affairs for ileostomy, colostomy and urostomy, design and set-up of the pivotal study for SUSHI (Urethral sphincter augmentation medium). Start-up of programmes for the metabolic support of ostomy patients, start-up of programmes for the development of medical devices in colo-rectal surgery; quality of life studies in anterior resection for rectal cancer, and in urinary and faecal incontinence.

Medical Director, Clintec Europe, a Baxter / Nestlé joint venture (1991-95)

Based in Slough, UK, and Milan, Italy. In charge of medical affairs in the UK, Benelux and Italy; business manager in Italy of the Home Parenteral Nutrition Service; medical member of the global R&D structure. Reporting to the Regional Vice President. Management of medical affairs for enteral and parenteral products, growth and differentiation of home TPN service in Italy. Product launches of peptide-based enteral nutrition solutions; innovative lipid emulsions; parenteral multivitamins; paediatric parenteral solutions, nutritional support in surgical, intensive care, inflammatory bowel disease, end stage renal failure patients.

Associate Medical Director, Baxter Italy (1986-90)

Based in Trieste, Italy. In charge of medical affairs for the Hospital Products, Clinical Nutrition and Blood Products Divisions. Reporting to the Medical Director. Management of medical affairs for specialised artificial nutrition solutions for paediatric, hepatic failure, renal failure, hypercatabolic patients; launch of blood conservation solutions, plasma expanders, drug delivery systems (infusors, implantable ports and catheters, patient-controlled analgesia in post-surgical pain control); championing of haemodilution and autotransfusion.

Occupational physician at Baxter Laboratories, Trieste, Italy (1986-90) Set up of the clinic and daily surgery for 520 employees at the manufacturing plant.

Clinical fellow, University Geriatric Hospital, Trieste (1983-86).

Set up and management of the Doppler ultrasonic vascular clinic, lecturing of internal medicine at the School of Physiotherapeutics, day-to-day patient care in the ward with special interest in depression and dementia in the elderly, nutritional status and peripheral arterial disease. Part-time locum General Practitioner throughout the period.

PROFESSIONAL QUALIFICATIONS

- Full Medical Registration in Italy (1983)
- Full Medical Registration in the UK (1993)

PROFESSIONAL BODIES

- General Medical Council (UK) No. 3703870
- Ordine dei Medici (Trieste, Italy) No. 2574

PROFESSIONAL SOCIETIES

- Past President of the Italian Medical Society of Great Britain (2014-2016)
- Council Member and Medical Affairs Consultant for the Gerson Lehrman Group (GLG)

INDUSTRIAL BODIES

- Past Chairman of the Professional Relations Working Group of the Clinical Nutrition Executive of IDFA (Infant and Dietetic Food Association) (2007-2008)

MEDICAL JOURNALS

- Editor-in-Chief of The Journal of Liver Research, Disorders & Therapy (JLRDT)

EDUCATION

- Postgraduate Course in Pharmaceutical Medicine, University of Wales, Cardiff (1999)
- Doctor of Medicine and Surgery, University of Trieste, Italy (1983) [110/110 cum laude]
- Certificate of Proficiency in English, University of Cambridge, UK (1975)
- Secondary education: Diploma of Classical Studies, Liceo Petrarca, Trieste, Italy (1971)