



Curriculum Vitae

Personal information **Niall MacAleenan**

Work experience

July 2020 - date

Director of Medical Devices, Health Products Regulatory Authority, Ireland

February 2018 – July 2020

Deputy Director of Medical Devices, Health Products Regulatory Authority, Ireland

June 2012 – February 2018

Medical Device Lead/Clinical Assessment & Policy Manager, Health Products Regulatory Authority, Ireland

June 2009 – June 2012

Clinical Assessment Manager, Human Products Authorisation & Registration

Health Products Regulatory Authority, Ireland

June 2007 – June 2009

Pre-Market Evaluation Manager, Medical Devices Department, Health Products Regulatory Authority, Ireland

June 2005 – June 2007

Medical Assessor of Medical Devices, Medical Devices Department, Health Products Regulatory Authority, Ireland

July 1999 – August 2004

Non-consultant hospital doctor (NCHD), Health Service Executive, Ireland

Education and training

September 2004-June 2005

Master of Business Administration

Michael Smurfit Graduate School of Business, University College Dublin
Ireland

September 1993 – June 1999

Bachelor of Medicine, Bachelor of Surgery, Bachelor of Obstetrics, Bachelor of Arts.

University of Dublin, Trinity College.

Additional information

Publications

1. Regulatory Assessment of Medical Devices in the European Union (book chapter)
International Society for Cardiovascular Translational Research. February 2019.
Alan G. Fraser, MD; Robert A. Byrne, PhD; Tom Melvin, MD; Niall MacAleenan, MD; Olga Tkachenko, PhD; Paul Piscoi, MD
2. A Competent Authority perspective on the new European medical device and *in-vitro* diagnostic legislation.
Journal of Medical Device Regulation. August 2017.
S Duggan, NF MacAleenan, Health Products Regulatory Authority. Ireland.
3. Challenges with Advanced Therapy Medicinal Products and how to meet them.
Nat Rev Drug Discov. 2010 Mar;9(3):195-201
Committee for Advanced Therapies (CAT); CAT Scientific Secretariat, Schneider CK, Salmikangas P, MacAleenan N
et al. European Medicines Agency, London
4. The role of colonoscopy in screening patients with low risk for colorectal carcinoma and non-specific colonic symptoms.
Eur J Gastro Hepatol. 2002 Oct;14(10):1073-7;
Abstract Gastroenterology 1998; 114(4): A557.
YS Ang*, NF Mac Aleenan*, D Kelleher, PWN Keeling, DG Weir.
Department of Clinical Medicine and Gastroenterology, St. James's Hospital, Dublin.
5. The role of colonoscopy in screening patients with rectal bleeding and low risk for colorectal carcinoma.
Presented at HRB Student presentations at the 8th National Scientific Meeting in the Royal College of Physicians.
YS Ang*, A McGrath, NF Mac Aleenan*, D Kelleher,
PWN Keeling, DG Weir. Department of Clinical
Medicine and Gastroenterology, St. James's Hospital,
Dublin.
6. Catheter related blood stream infection rates among haematology and oncology patients attending St. James's Hospital.
Presented at Haematology Associated of Ireland Annual Meeting 2003.
NF Mac Aleenan, A O'Brien, M Kelleher, PA Daly, SR McCann, B O'Connell.
Departments of Haematology, Oncology and Clinical Microbiology, St. James's Hospital,
Dublin.
7. *Helicobacter pylori* – Secondary resistance rates in cases of previous treatment failure.
NF Mac Aleenan, PWN Keeling, B O'Connell.
Departments of Gastroenterology and Clinical Microbiology, St. James's Hospital,
Dublin.

Projects

Memberships

Other Relevant Information