



Curriculum Vitae

Personal information Benjamin Micallef

Work experience

1. Employer: Malta Medicines Authority
 - Start date: 042022
 - End date:
 - Position: Senior Head (Pharmacovigilance, Medicines Safety, and Regulatory Support
 - Activities: Manage procedures related to post_licensing and pharmacovigilance as well as review scientific documentation and reports; Manage procedures related to the collection, detection, assessment, monitoring, and prevention of adverse effects with medicinal products; Regulate the advertising of medicinal products for human use as laid down in the advertising regulations; Contribute to, and oversee the assessment and supervision processes for clinical trials, via the Clinical Trials Information System (CTIS); Supervise assigned individuals and monitor regulatory projects within the Post_Licensing Directorate; Implement budgetary and simplification measures as required; Provide financial budgets and management. Ensure that operations are efficient and cost effective; Represent the Malta Medicines Authority at meetings, seminars, conferences and other fora, both locally and abroad. Develop and oversee implementation of business continuity plans across the Post_Licensing Directorate; Prepare and produce accurate detailed reports of activities of the Malta Medicines Authority; Monitor and report performance against the key performance indicators and support continuous improvement of performance for the areas pertaining to post_licensing of medicines; Addressing pharmaceutical queries raised by Ministries and other entities; Monitoring and follow_up of queries and complaints and ensure that quality services are provided to all stakeholders; Ensure post_licensing activities meet requirements in terms of accuracy, completeness, timeliness and financial planning; Ensure adherence to relevant EU and national legislation, public administration policies, regulatory requirements and the quality management system of the Malta Medicines Authority; Ensure that employees receive the necessary training to achieve their potential, by using delegation and empowerment to provide opportunities to develop their competencies.
 - Country: Malta
2. Employer: Malta Medicines Authority
 - Start date: 082019
 - End date:
 - Position: Head (Pharmacovigilance)
 - Activities: Establish procedural needs of the Directorate and ensure effective and efficient management of Pharmacovigilance processes; Ensure implementation, maintenance and reporting on the progress of procedures; Lead continuous improvement of core business processes in Pharmacovigilance; Support upper management in the day to day operations by monitoring and reporting performance against the key performance indicators as well as providing required training to staff; Assist and provide support to the Director, Post_Licensing in all functions.
 - Country: Malta
3. Employer: Malta Medicines Authority
 - Start date: 022018
 - End date: 082019
 - Position: Senior Pharmacist
 - Activities: In addition to activities from previous position as Pharmacist at the Medicines Authority; Product co_ordinator for Periodic Safety Update Report single assessment (PSUSA) procedures where Malta is the Lead Member State Management of Safety Recalls Delivering Technical Induction Training to new staff and students
 - Country: Malta
4. Employer: Malta Medicines Authority
 - Start date: 062016
 - End date: 022018
 - Position: Pharmacist
 - Activities: Compilation and distribution of Safety Circulars Management of Rapid Alerts and Non_Urgent information related to pharmacovigilance Management of Direct Healthcare Professional Communication (DHPC) and joint DHPC service Routine Signal Management Management of Pharmacovigilance Queries and Annual Query Reports, Management of incoming adverse drug reaction (ADR) reports ADR reporting promotion Updating Standard Operating Procedures & business process mapping Experience in IT/Telematics systems available to Member States to support the operation of pharmacovigilance in the EU.
 - Country: Malta
5. Employer: Community Pharmacies
 - Start date: 102015
 - End date:
 - Position: Locum Pharmacist
 - Activities: Dispensing Medicines to patients, Patient Counselling, Participating in Pharmacy Of Your Choice (POYC) scheme, other pharmacy related tasks
 - Country: Malta

Education and training

1. Subject: University of Malta in collaboration with the University of Chicago at Illinois

- Start date: 102015
 - End date: 092018
 - Qualification: Pharm.D.(Melit.)
 - Organisation:
 - Country: Malta
2. Subject: University of Malta
- Start date: 102014
 - End date: 102015
 - Qualification: M.Pharm.(Melit.)
 - Organisation:
 - Country: Malta
3. Subject: University of Malta
- Start date: 102010
 - End date: 102014
 - Qualification: B.Sc. (Hons) Pharm. Sc.(Melit.)
 - Organisation:
 - Country: Malta

Additional information

Publications

1. Curtolo E, Micallef B, Szijj JV, Serracino-Inglott A, Borg JJ. An exploratory study of knowledge, attitudes, practice and barriers towards adverse drug reaction reporting among healthcare professionals in Malta. *Int J Risk Saf Med.* 2024;35(3):271-286. doi: 10.3233/JRS-230055
2. Debono J, Balzan D, Borg JJ, Falzon S, Al-Haddad D, Micallef B, Sultana J. Nivolumab Safety in Renal Cell Carcinoma: A Case Report. *J Pharm Technol.* 2024 Apr;40(2):112-117. doi: 10.1177/87551225231218164.
3. Micallef B, Dogné JM, Sultana J, Straus SMJM, Nisticò R, Serracino-Inglott A, Borg JJ. An Exploratory Study of the Impact of COVID-19 Vaccine Spontaneous Reporting on Masking Signal Detection in EudraVigilance. *Drug Saf.* 2023 Nov;46(11):1089-1103. doi: 10.1007/s40264-023-01346-9.
4. Melchiorri D, Merlo S, Micallef B, Borg JJ, Dráfi F. Alzheimer's disease and neuroinflammation: will new drugs in clinical trials pave the way to a multi-target therapy? *Front Pharmacol.* 2023 Jun 2;14:1196413. doi: 10.3389/fphar.2023.1196413.
5. Tanti A, Micallef B, Vella Szijj J, Serracino_Inglott A, Borg JJ. QT shortening: a proarrhythmic safety surrogate measure or an inappropriate indicator of it? *Curr Med Res Opin.* 2022 Sep;38(9):1473_1483. doi: 10.1080/03007995.2022.2083401. Epub 2022 Jun 14. PMID: 35621140.
6. Micallef B, Nistico R, Bjerrum OW, Sarac SB, Butler D, Serracino_Inglott A, Borg JJ. Outcomes and endpoints in clinical trials supporting the marketing authorisation of treatments in paediatric acute lymphoblastic leukaemia. *Drug Discov Today.* 2022 Sep;27(9):2440_2466. doi: 10.1016/j.drudis.2022.05.015. Epub 2022 May 18. PMID: 35597514.
7. Micallef B, Nisticò R, Sarac SB, Bjerrum OW, Butler D, Sammut Bartolo N, Serracino_Inglott A, Borg JJ. The changing landscape of treatment options in childhood acute lymphoblastic leukaemia. *Drug Discov Today.* 2022 May;27(5):1483_1494. doi: 10.1016/j.drudis.2022.01.002. Epub 2022 Jan 7. PMID: 35007767.
8. Zuccarelli M, Micallef B, Butler D, Serracino_Inglott A, Borg JJ. Improving the data quality of spontaneous ADR reports: a practical example from Malta. *Expert Opin Drug Saf.* 2022 Feb;21(2):253_268. doi: 10.1080/14740338.2022.1993820. Epub 2021 Oct 22. PMID: 34649475.
9. Butler D, Vucic K, Straus S, Cupelli A, Micallef B, Serracino_Inglott A, Borg JJ. Regulatory experience of handling Risk Management Plans (RMPs) for medicinal products in the EU. *Expert Opin Drug Saf.* 2021 Jul;20(7):815_826. doi: 10.1080/14740338.2021.1909569. Epub 2021 Apr 22.
10. Zuccarelli M, Micallef B, Cilia M, Serracino_Inglott A, Borg JJ. The EU regulatory network and emerging trends – a review of quality, safety and clinical development programmes. *Generics and Biosimilars Initiative Journal (GaBI Journal).* 2021;10(2):83_99.
11. Mifsud Buhagiar L, Micallef B, Borg JJ, Vella H, Serracino_Inglott A, LaFerla G. Regulatory sciences and translational pharmacogenetics: amitriptyline as a case in point. *Drug Metab Pers Ther.* 2019 May 30;34(2). pii: /j/dmdi.2019.34.issue_2/dmpt_2019_0005/dmpt_2019_0005.xml. doi: 10.1515/dmpt_2019_0005.
12. Mifsud Buhagiar L, Casha M, Grech A, Micallef B, Borg JJ, Serracino_Inglott A, LaFerla G. Safety Implications of Low_Dose Amitriptyline in Neuropathic Pain. *Pharm Front.* 2019;1:e190003. https://doi.org/10.20900/pf20190003
13. Borg JJ, Melchiorri D, Sepodes B, Caramella CM, Tomino C, Micallef B, Nistico R. Optimising bench science to withstand regulatory scrutiny. *Pharmacol Res.* 2018 Oct 12. pii: S1043_6618(18)31563_9. doi: 10.1016/j.phrs.2018.10.014.
14. Tanti A, Camilleri M, Borg AA, Micallef B, Flores G, Serracino_Inglott A, Borg JJ. Opinions of Maltese doctors and pharmacists on medication errors. *Int J Risk Saf Med.* 2017;29(1_2):81_99. doi: 10.3233/JRS_170741.
15. Tanti A, Micallef B, Serracino_Inglott A, Borg JJ. A review of the National pharmacovigilance system in Malta _ implementing and operating a pharmacovigilance management system. *Expert Opin Drug Saf.* 2017 Jan;16(1):65_76. Epub 2016 Oct 24.
16. Micallef B, Attard E, Serracino_Inglott A, Borg JJ. Could EU herbal monographs contribute to Malta's treatment armamentarium? *Phytomedicine.* 2015 Mar 15;22(3):400_5. doi: 10.1016/j.phymed.2015.01.005. Epub 2015 Feb 26.

Projects

Memberships Registered Pharmacist in Malta

Other Relevant Information