PEOPLE – QUALITY – INTEGRITY – INNOVATION

THE MALTA MEDICINES AUTHORITY INTERNATIONAL FELLOWSHIP PROGRAMME

The Malta Medicines Authority invests heavily in its people and in capacity building of the Maltese pharmaceutical sector. Ten percent of its budget is dedicated to learning and development.

The key objectives of the programme are to:

- assist people to pursue further levels of academic research;
- reduce skills mismatches particularly within the pharmaceutical and life sciences sector;
- contribute to the consolidation of expertise on emerging and challenging topics relevant to innovative therapies and technologies;
- increase the capacity and level of research, innovation and development activity in Malta and the EU;
- support the implementation of the MMA 2016-2020 Strategy and the Framework for Education Strategy for Malta 2014-2024.

More information on how the Malta Medicines Authority can support you in getting your Masters and Doctorate degree is available on www.medicinesauthority.gov.mt

Our vision is to be a centre of excellence in advancing effective and innovative regulation and promoting quality and scientific rigour in the work we do. We strive to be a best in class regulator for the benefit of patients and stakeholders. We endeavour to be an internationally recognised, efficient entity and promoter of people development and sustainable growth.

Malta Medicines Authority,
Sir Temi Żammit Buildings,
Malta Life Sciences Park,
San Ġwann, SĠN 3000, Malta

info.medicinesauthority@gov.mt
(+356) 23 439 000

www.medicinesauthority.gov.mt

Printed in 2017

MALTA'S KEY REGULATORY

and Scientific Competent Authority in the Pharmaceutical Sector

MALTA
MEDICINES
AUTHORITY

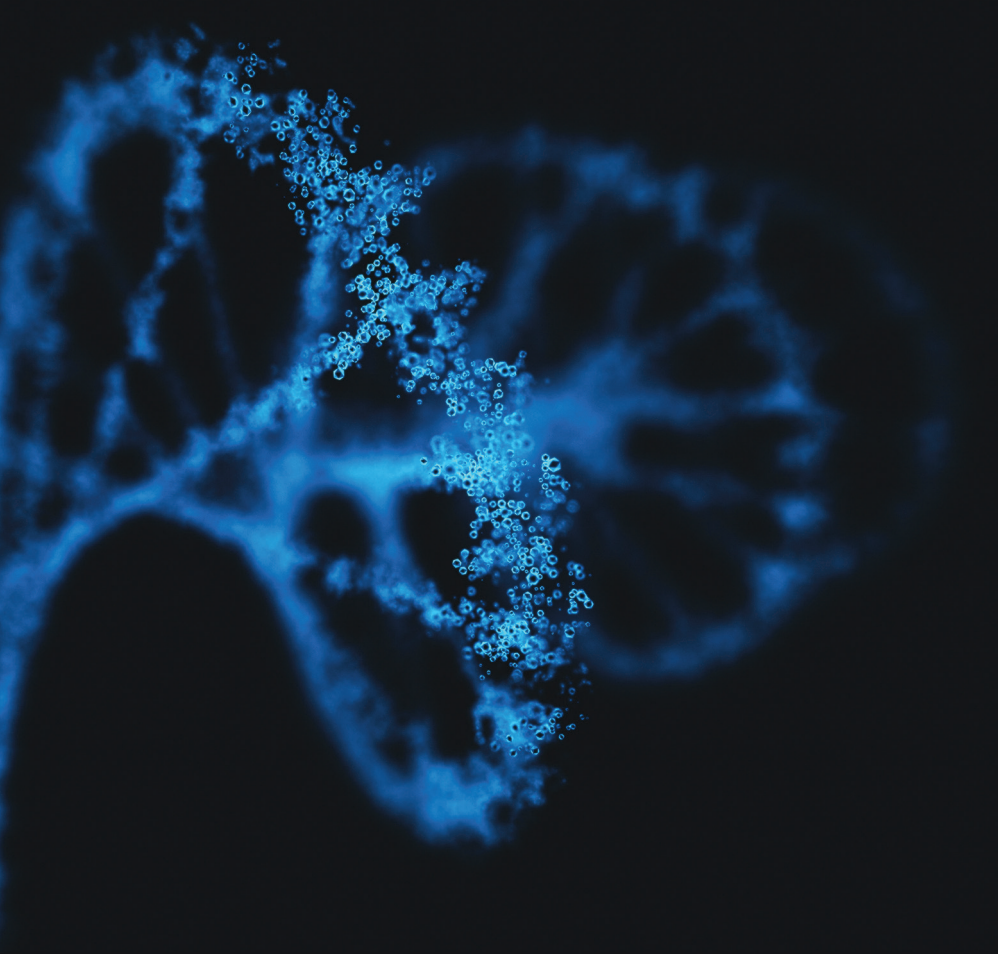
EVALUATION AND AUTHORISATION OF MEDICINAL PRODUCTS

Every medicinal product is granted a marketing authorisation before being placed on the market based on a positive risk/benefit assessment of quality, safety and efficacy according to EU and National legislation.

The Malta Medicines Authority (MMA) processes applications for marketing authorisations and post-authorisation activities for all medicinal products. Malta has ranked amongst the top EU countries in the assessment of medicines through the European procedure. The Authority provides guidance and scientific advice to support the development of products and technologies. The MMA is responsible for the constant monitoring of the safety of medicines after authorisation and has recently increased capacity to cater for safety assessments.

Malta as a European Union (EU) Member State accepts applications to act as Reference Member State (RMS) for European Procedures to authorise medicinal products for the first time in the EU.

300 Marketing Authorisations issued by the Malta Medicines Authority with Malta as Reference Member State



EVALUATION AND AUTHORISATION OF CLINICAL TRIALS

Malta has one of Europe's most modern integrated general hospitals including a new Oncology Centre. The Malta Life Sciences Park includes the new state-of-the-art offices of the Malta Medicines Authority. As a country with relative genetic homogeneity, Malta is an ideal place to perform specialised clinical trials and is also a referral centre for a number of regionally significant diseases such as cardiovascular, diabetes, oncology and obesity.

The Malta Medicines Authority welcomes applications for Clinical Trials

REGULATION OF PHARMACEUTICAL ACTIVITIES

The Malta Medicines Authority adopts a supportive, consistent and transparent regulatory approach

The Authority has acquired a sound reputation for providing all the services required by the local pharmaceutical companies efficiently and cost effectively. These include the conduct of inspections of clinical trials (GCP), distribution (GDP), manufacturing plants and laboratories (GMP) and Pharmacovigilance (GVP), in accordance with the principles and guidance of EU Good Practices (GxP).

Certification is granted in a timely manner to suit the operator's start up plans based on established communication between the parties involved.

The Authority carries out third country GMP inspections throughout the year and has recently extended its capacity to cater for increased demand in sterile manufacturing and radiopharmaceuticals amongst others.

76 GMP Sites Certified
by the Malta Medicines Authority

Contact Mark Cilia on inspectorate.adm@gov.mt to discuss your development proposal and reserve your personalised inspection slot.