SOMETHING SPECIAL IS HAPPENING IN IRELAND



by John Johnson and Robyn Meurant

Despite a decade of an economy that at times felt like a rollercoaster, the pharmaceutical and medical technology industry in Ireland continues to grow strongly. A multitude of factors has contributed to this rapid evolution, and the country can look back with some satisfaction in terms of harnessing a variety of committed and energetic government agencies that are active in promoting life sciences alongside the development of a stable, highly educated workforce.

The numbers speak for themselves (see figure 1).

NSF INVOLVEMENT

NSF is proud to have played a part in that growth with:

- Assignments concerning facility design, qualification and operational support for both sterile and non-sterile production units.
- > Audits, remediation plans and extensive internal training activities in Ireland and Northern Ireland.
- > Over 75 delegates from Ireland pharma companies attending our public training courses in Manchester, York and Amsterdam.



In 2019, we plan to extend the range of services that are easily accessible to the Irish pharma and med tech sector so that:

- > We run more internal training and education programs on-site as internal, customized events.
- We have a factory-based course, GMP for Biological and Biotechnology Products, allowing more hands-on, practical interpretation of GMP at the shop floor and management levels (visit www.nsf.org/info/pharma-training) as announced in the last Journal. John Johnson and Roger Guest are the expert tutors for this course at NIBRT (Dublin) 17-20 September 2019.
- > We are expanding our local expertise and network to keep closer to the areas of innovation and investment.
- > We are available to offer expert advice on meeting the demanding new requirements and impending timelines of the new EU regulation for medical devices and IVDs.

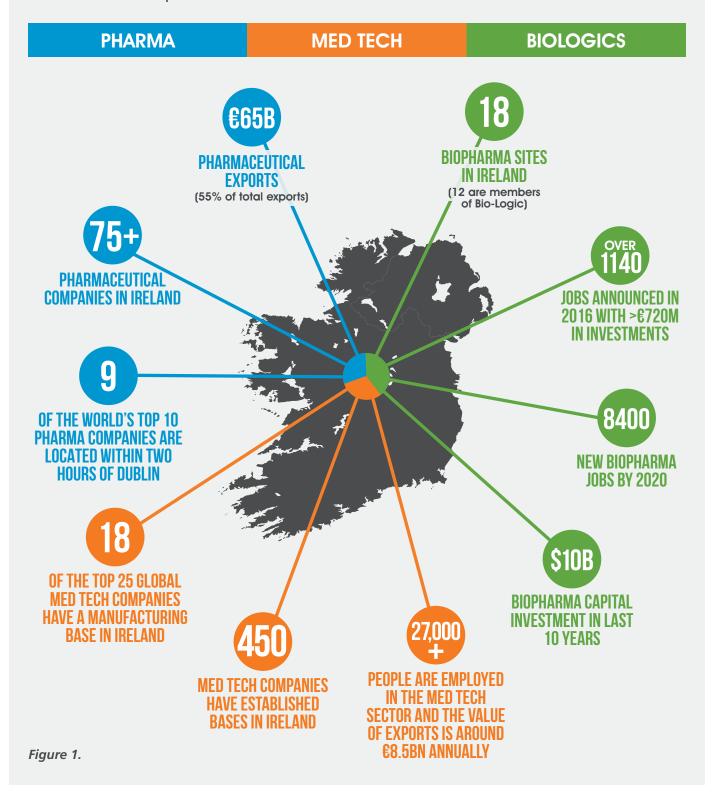
LOOKING AHEAD

Some key features characterize this sector and we aim to combine our medical devices and pharma expertise to meet the challenges ahead, e.g.:

- > More user-friendly (and often more complex) drug delivery systems.
- > More combination products.
- > An expansion in biosimilars as well as biologically active materials for some of the world's most challenging illnesses.
- > A younger workforce that demands a different level of engagement and inspiration; not least that the learning and deployment style appears a step change away from those of us who joined the industry in the 1980s and 1990s.



Growth of Biopharma and Med Tech: Ireland



Howard Broadbridge (Practice Manager, Medical Devices), Robyn Meurant (Executive Director, Medical Devices) and John Johnson (Vice President, Pharmaceutical Services) have been working closely with some existing and potential clients, government agencies and universities to study the conditions that have led to such a surging growth, alongside a growing

reputation for GMP compliance, in Ireland. They are studying the success factors and holding them up against the challenges ahead, such as:

- > How can this growth be sustained?
- > Where will the industry leaders be created and how?



- Where will all these new employees come from and how can they be inspired to engage with such a highly regulated industry to achieve perpetual GMP compliance as well as promote innovation?
- How will the startups and new facility builds move from construction or development to commercial facilities; what skills will they need?
- > How will the Irish facilities compete in the global market perhaps utilizing razor sharp quality risk management, management of quality costs and refinement/maturation of the quality system?
- > How ready are Irish manufacturers for the EU MDR and the IVDR?

It is an exciting time for us at NSF, combining locations and competencies across pharma and med tech, leveraging our expertise and experience so that we support our clients' expansion plans. In the coming Journals, we will share some case studies of our work in this field, helping you to see how you might take your operation to the next level.

ABOUT THE AUTHORS



John Johnson is passionate about helping organizations foresee and overcome the barriers to sustainable long-term growth. He brings 28 years' experience across a range of

companies in the pharmaceutical and healthcare industry. He has worked in small, medium and large pharma biotech companies across the product lifecycle for a wide range of dosage forms.



Robyn Meurant has more than 30 years of experience in the field of IVDs, as a laboratory scientist and as a regulator with the Australian Therapeutic Goods Administration

(TGA) and with World Health Organization (WHO) Prequalification. Ms. Meurant began her career working in several large diagnostic laboratories in the role of senior scientist. In her position at TGA, Ms. Meurant assisted in developing the new regulatory framework for IVDs. With WHO, she served as the lead technical officer for application evaluation and dossier assessment, and as lead for the development of guidance and technical specifications for IVDs in the scope of WHO Prequalification.

Copyright © 2019 NSF International.

This document is the property of NSF International and is for NSF International purposes only. Unless given prior approval from NSF, it shall not be reproduced, circulated or quoted, in whole or in part, outside of NSF, its committees and its members.

Cite as: NSF International. May 2019. Something Special is Happening in Ireland. NSF: York, UK.

NSF INTERNATIONAL | HEALTH SCIENCES

The Georgian House, 22/24 West End, Kirkbymoorside, York, UK YO62 6AF **T** +44 (0) 1751 432 999 | **E** healthsciences@nsf.org

789 N Dixboro Rd, Ann Arbor, MI 48105, USA **T** +1 202 822 1850 | **E** healthsciences@nsf.org