

A new year with new challenges

BOB CLAY, TOPRA PRESIDENT

Welcome to 2017 and my first InTouch editorial as President of TOPRA. Following the tradition set by past presidents, I will use this first editorial as an opportunity to introduce myself and share some reflections

I would like to thank you all for your continuing support for TOPRA as the professional membership organisation representing the interests of both members and the wider community. I acknowledge the support of the Board (both old and new) and of Thomas Kühler, Past-President; continuity is important in the development of our organisation and I fully endorse the strategy developed by the Board over the past few years.

However, our profession and our society will face new challenges for which we must be willing to adopt novel solutions that build on the solid foundation formed over many years.

It is more than 30 years since I qualified as a pharmacist in the UK. My first experience of regulatory affairs was as a formulation scientist and then as a pharmaceutical reviewer during the 1980s. At this time the regulation of medicines was managed nationally with only limited international cooperation.

In 1996, while at Pfizer,

I was involved in the first of several centralised submissions based on a global development programme filing simultaneously in the US and the EU. This submission was also built electronically, delivered to EU and US regulators on a laptop to the regulatory reviewers.

It is now routine for large and mid-size pharmaceutical companies to submit in multiple countries and most regions of the world within weeks of the first submission, and overall review times have been reduced.

The level of partnership between regulators has also increased, not only in the development of guidelines but also in the review of applications and post-approval monitoring. Regulators have developed their role from gatekeeper to active participants in the innovation process and this is represented in the emergence of “regulatory science”.

While at Pfizer from 1993–2008, and subsequently at AstraZeneca from 2008–2014, I had the opportunity to see the growth and evolution of our



profession from a liaison function between internal teams and the regulatory authority, to a range of disciplines including regulatory intelligence, regulatory operations, regulatory strategy and an ever-closer collaboration between regulatory and safety functions.

In many cases, these functions have combined to support both development and commercial operations, allowing regulatory professionals to contribute in many ways and build meaningful and rewarding careers.

During my term as President of TOPRA I hope to meet many members to further understand the needs of the profession, and alongside the Board build on the work of the past leadership and our fabulous team in the London office.