



# LYNNE BYERS' 40 YEARS IN THE INDUSTRY



**Our Executive Director, Lynne Byers, celebrated 40 years in the pharmaceutical industry in July. We have taken the opportunity to interview her about her long service.**

## WHAT WAS YOUR FIRST JOB?

My first job was as a Junior Laboratory Assistant at the GSK site in Barnard Castle, England. I spent two weeks learning how to do titrations, weighing and all the basic tests while the factory was shut down. Three of us started at the same time and we were trained in the laboratory techniques by a lady called Joan Martin. My first job was to work in the raw materials laboratory testing APIs, excipients and other raw materials such as solvents.

## WHAT MAJOR DIFFERENCES DO YOU SEE BETWEEN WORKING IN AN INCOMING MATERIALS LABORATORY IN 1978 AND TODAY?

Many of the tests are the same, but the techniques differ. One surprising thing is that we did not have methods then; we worked directly from the pharmacopoeias and had to work out concentrations, etc. There were also no computers, emails or mobile phones. GC and HPLC were in use, but without computers we had to measure the peak sizes with rulers and do all calculations manually. At least we had electronic calculators. There were no printouts from balances or pH meters. Everything was recorded manually, and all calculations were checked by a second person. So, there are some differences and some similarities with what still happens today. The biggest difference is the use of computing and even robots in today's QC laboratories.

## WHERE DID YOUR CAREER TAKE YOU?

After 10 years in various laboratories and gaining my degree in chemistry, I moved to an operational quality role in an oral solid dose/aseptic filling operation. I then

started to study for my Qualified Person qualification. I even did a couple of modules of the DBA (now NSF) training course. I became Head of Quality for the cephalosporins product stream. After moving into a role managing GMP education, 'intelligence into action' and supplier quality management, I moved from the north to the south of the UK and became Quality Director for another GSK site. I then left GSK and joined the MHRA as Head of Inspectorate and Licensing. This was a fantastic opportunity where I led the UK GxP inspectorates and saw how the regulators work. After a couple of years, I moved back to industry and worked for UCB where I was responsible for global quality strategy, including developing a GxP PQS. Next GSK tempted me back and I became VP, Head of Shared Services and Supplier Quality. I then moved from the UK to Switzerland where I was appointed as Global Head (VP) of Country QA and then Global Head (VP) of External Supply at Novartis. My latest move saw me moving back to the UK and working as Executive Director for NSF. I am now living about 15 miles from where I started my career.

## WHAT ADVICE WOULD YOU GIVE TO ANYONE STARTING THEIR CAREER IN THE PHARMACEUTICAL INDUSTRY?

Enjoy it. As an industry we help save and improve peoples' lives so there is a real sense of achievement. As someone who has spent all my career in quality or as a regulator, it is a privilege to work in the pharmaceutical industry. Get as much experience as possible from working in manufacturing or various parts of QA and QC.

## MY TOP 10 TEAM EVENT MEMORIES

The people we work with are important no matter which industry we work in.

1. A cruise on Windermere, UK.
2. River cruises on the Thames, England and Chesapeake Bay, USA.
3. A buffalo cart ride in Poland.



4. Visiting the pyramids on a business trip to Egypt.
5. Team events on the London Eye.
6. Going on a cable car to the Great Wall of China in a gale.
7. Teambuilding cooking in Paris, Singapore and Basel.
8. Being led blindfolded across a table tennis table in Switzerland.
9. Practicing a team song in a bandstand in Brighton, UK.
10. Going to a baseball match in the USA.

I would love to hear from anyone who was also at the events listed above ([lynnebyers@nsf.org](mailto:lynnebyers@nsf.org)).

## WHAT DO YOU SEE AS INTERESTING CHALLENGES FOR THE INDUSTRY BOTH NOW AND IN THE FUTURE?

I see a few challenges now that will probably continue in the future.

The first is how to make it easy to comply with regulations or processes. A saying I coined is "One person's perfect process is another person's bureaucracy." Sometimes as an industry we spend so long developing very detailed processes we forget the big picture and to include input from the people who need to implement or follow the processes. The challenge is to not update procedures or policies every time there is a regulatory finding, but to look for the true root causes. So often I see very complicated processes and procedures which are almost impossible to follow. The efforts to have simple yet compliant processes and procedures will continue.

The second is how to have and retain confidence in the ever-growing complexity of supply chains. So often regulators publish warning letters or non-compliance reports for companies. Customers of those companies are left with a lack of APIs or products. However, for a QA person there is often some soul searching about how did I/we miss it? What should I do now? The cooperation between regulators is very welcome and I predict an increase in that cooperation.

Personalized medicine is also a current challenge and will become more so. How should the industry manage the quality assurance of advanced therapeutic medicinal products, such as cell and gene products? How do systems ensure vein-to-vein traceability from the patient and back to that same patient? What level of risk is appropriate when the product is potentially life-saving? These questions will demand different thinking from quality professionals and the industry as a whole.

## WHAT DO YOU ENJOY DOING OUTSIDE WORK?

I like travelling and take my full holiday entitlement! This year I have been to Switzerland, Norway, Iceland, Greenland, Canada and Portugal, and am going to India in November.

I also like going to the theatre and can walk to my local theatre from my house. I am also interested in history and like visiting historical houses, castles and museums.

For more information, contact [pharmamail@nsf.org](mailto:pharmamail@nsf.org) or visit [www.nsfpharmabiotech.org](http://www.nsfpharmabiotech.org)

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