SO WHAT ARE THE KEY CHALLENGES TO THE PHARMA INDUSTRY RIGHT NOW? YOU TOLD US!

It was fantastic to meet so many new and existing clients at Making Pharmaceuticals at the Ricoh Arena in Coventry on 25-26 April. The stream of interest in our services kept Mike Halliday, Peter Gough, John Johnson and Sam Richardson busy from dawn to dusk.

We love to hear what you are working on, discuss your challenges and work out pragmatic ways of overcoming the obstacles that dog the path to long-term, sustainable success in your business. We are in a unique position in working with the brightest and most active minds in the business, engaging with a wide variety of organisations that seek to make breakthrough changes to their current standards of financial performance, customer service, product quality and GMP compliance. We know how it feels to be in your shoes right now and we know hard it is to respond to a new phase in pharma history where:

- Discontinuous change and paradigm shifts are the norm
- Uncertainty is certain
- Legacy and reputation are critical to your business, though the challenges facing us make preserving your legacy harder than ever
- Trust and long-term relationships are under strain as everyone seeks flexibility, responsiveness and value in every transaction

We realise that many of the norms, especially those that you as leaders relied on in your early careers, have changed and will change again. NSF Health Sciences are in-step with these trends and are here to help your organisation evolve and flourish, despite the pulling and pushing forces that lie ahead.

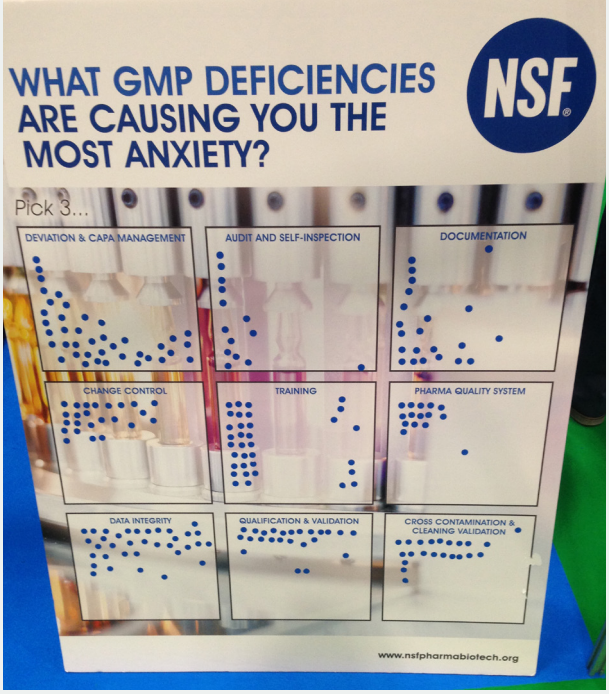
Many of you came along to our presentations:

Tuesday 25th April: John Johnson
What Organisational Behaviours Drive Perpetual Adherence to cGMP?

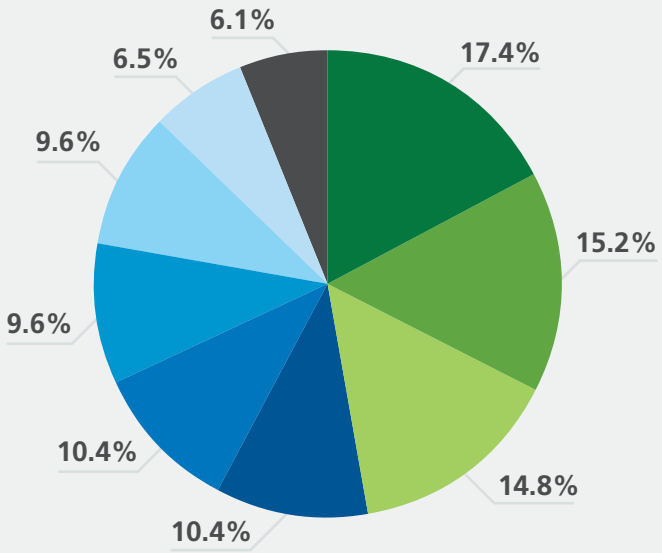
Wednesday 26th April: Peter Gough
Brexit; The Potential Impacts for Pharmaceuticals

If you would like a copy of these presentations please contact us at **srichardson@nsf.org.**

Our stand seemed to ring so many bells too, and as you remember, we asked you three key questions and gave you the opportunity to contribute answers. As promised, here's the feedback from all of the thought leaders, entrepreneurs, department heads and subject matter experts who visited the stand and contributed to the discussion:



WHAT GMP DEVIATIONS ARE CAUSING YOU THE MOST ANXIETY?

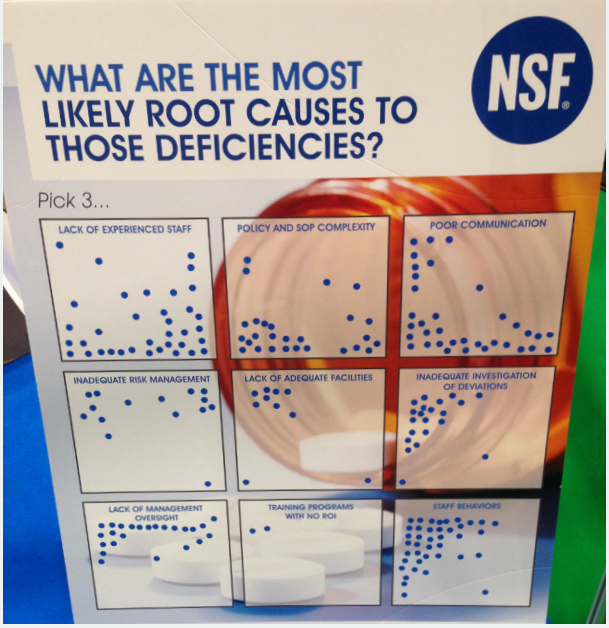


OUR COMMENTARY:

A third of you see deviation and CAPA management, data integrity and staff training as areas of real heartache, with an almost equal spread of concern across the other areas. On discussion, many of the contributors agreed that the skills needed to perform an effective root cause analysis and an open blame-free investigation as well as to generate a cogent technical report still appear in acute short supply. Never before has training of staff in the 'know why' been as important as the 'know how'. Many agreed that their internal training programmes have been eroded due to tighter budgets, less internal expertise and a squeeze on time allocated to education programmes. Many of you mentioned that a new, highly focused, interactive learning style is needed if we are going to inspire and engage a new generation of people to join the industry and become the leaders of the future.

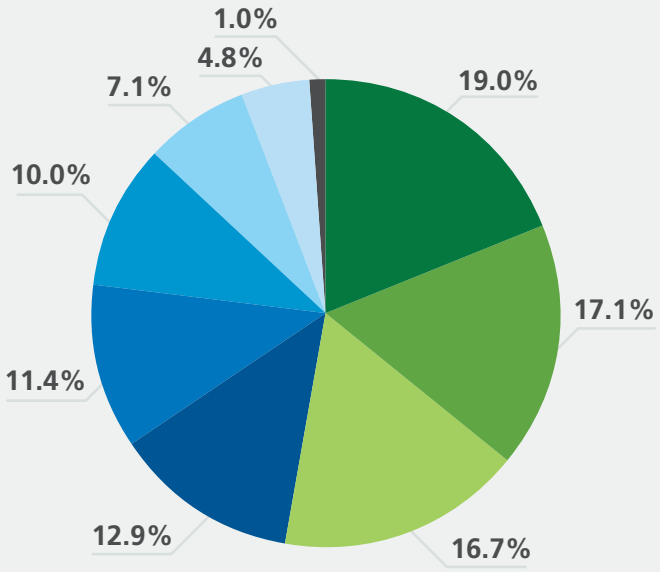
See also:

- > Video: How to Educate, Not Train
- > Video: How to Reduce Repeat Deviations, Errors and Mistakes
- > Webinar: How to Stop Making the Same Mistakes



THEN WE ASKED:

WHAT ARE THE MOST LIKELY ROOT CAUSES TO THOSE DEFICIENCIES?



OUR COMMENTARY:

Surprising to some of you perhaps, the industry does not appear to have issues with items requiring good science, but it has significant issues with its staff expertise and behaviours where more than half of you felt that the heartache being felt is largely attributable to staff behaviours, lack of experienced staff and poor communication. On discussion, it was clear that disengaged, poorly managed staff only perpetuate poor behaviours and low performance, and failing to inspire and invest in staff at all levels can lead to unpredictability and volatility across the quality system. A key part of leadership is the mentoring and investment in staff, getting the best from every team member and ensuring that they can contribute heavily in the future of the organisation.

A key area that appears to switch everyone off is over-complexity of policies and procedures, and we are aware too that the regulators are hugely concerned that the industry is still failing to comply with cGMP in large part due to a burdensome, over-complex approach to quality assurance and cGMP compliance. A system with many moving parts and lots of transactions, designed for every eventuality and written by managers not the user group is commonly a root cause of non-compliance and we are working with many firms to improve their quality system by streamlining and simplifying the messaging, the standards, the signals and the key actions needed. Remember, complexity feeds non-compliance:

> Video: How to Jumpstart Your Pharma Business by Simplifying Processes

> Webinar: Changing GMP Behaviours and the Quality Culture

So what did you say the industry should be doing more of:

These can be summarised as:

Action	Weighting from the respondents
Invest in staff education at all levels	High
Simplify systems and procedures	High
Utilise risk management to focus on the priorities	High
Invest the time for more face to face two-way communication	Medium

So as part of your quality planning for 2017/18, and considering your organisational development budget for the year ahead, how will you seek to improve in these key areas?

Why not test yourself and write down exactly what you will do to raise the bar in these areas; how will you help yourself and your team become the best version of itself in the next 12 months.

Keep in touch with NSF Health Sciences; visit **www.nsfpharmabiotech.org**, email **pharmamail@nsf.org** or call **+ 44 (0) 1751 432 999**

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