

Journal

2017, Issue 37

The right people. The right solution. The first time.™



New Year
New Habits
Less Stress



Health Sciences
Pharma Biotech
Consulting

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welcome

Welcome to the first Journal of 2017. This edition focuses on how to change behaviors. After all, 2017 will be very different from previous years. New challenges will require new behaviors. Clients who attend our training courses or use our consultancy services tell us we're different because we help improve performance by changing behaviors, not by adding complexity. Read on to find out how.

I'm privileged to work with the best. People who genuinely care about making a difference. Well, here they are. Together with their 2017 promises!



Martin Lush



Martin Lush
*President, NSF Health Sciences
Pharma Biotech Consulting*

"To complete the UK Ironman 2017 in under 12 hours."



John Johnson
*Executive Director, NSF Health
Sciences Pharma Biotech, UK*

"To catch a 20lb Atlantic Salmon in Scotland on the fly – that would be a lifetime achievement!"



Andrew Papas
*Vice President of Regulatory Affairs
Pharma Biotech, US*

"Increase my bicycling mileage and improve my novice skiing technique."



Pete Gough
*Executive Director, NSF Health
Sciences Pharma Biotech, UK*

"To spend at least one week in every quarter with each of my grandsons."



Maxine Fritz
*Executive Vice President, NSF Health
Sciences Pharma Biotech, US*

"To spend more time with my husband."



Rachel Carmichael
*Executive Director, NSF Health
Sciences Pharma Biotech, UK*

"To work on my spoken French."



Mike Halliday
*Vice President, NSF Health Sciences
Pharma Biotech, UK*

"I'd like to help my sons safely explore high places and reach new heights."



Jesse Ahrendt
*Executive Director, NSF Health
Sciences Pharma Biotech, US*

"To be able to keep up with my six-year-old son skiing down black diamond-rated slopes."



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Anne Davies
Client Project Manager, NSF Health Sciences Pharma Biotech, UK

“With the purchase of a new bike in 2016, I hope to complete a 30-km ride somewhere in Europe, which will be a challenge for me with drop handle bars!”



Rocco Duran
Executive Director, NSF Health Sciences Pharma Biotech, US

“To focus on my health and spend more time with my family.”



Nicholas Markel
Executive Director, NSF Health Sciences Pharma Biotech, US

“After 12 years of living in Oregon, to finally visit Crater Lake.”



Andrew Barnett
Director of Quality Systems, NSF Health Sciences Pharma Biotech, US

“To get back in touch with old friends.”



Jim Morris
Executive Director, NSF Health Sciences Pharma Biotech, US

“To bike Vermont south to north.”



Stella Pearson-Smith
Office Manager & QP Administrator, UK

“To eat less cake.”



Shritin Shah
Executive Director, NSF Health Sciences Pharma Biotech, US

“To continue to lose weight that I have gained while traveling for projects.”



Mairin Walters
Director of Operations, Pharma Biotech Consulting, US

“To learn to speak Italian.”



Marinka Tellier
Director, Regulatory Affairs, NSF Health Sciences, US

“To fly a spinnaker on Chesapeake Bay.”



Heather Taylor
Marketing Director, NSF Global Health Sciences, BE

“Learning the Argentine tango in Buenos Aires. Oh! If only I had the legs too!”



George Toscano
Vice President of Quality Systems, NSF Health Sciences Pharma Biotech, US

“To spend more time with my family.”



Deborah Cuming
Senior Accountant, NSF Health Sciences Pharma Biotech, UK

“To take a flight in a glider.”



by Martin Lush,
President, NSF
Health Sciences
Pharma Biotech
Consulting

CHANGING YOUR QUALITY CULTURE AND IMPROVING GMP BEHAVIORS:

What Works and What Doesn't

Ever wondered why 70 percent of change initiatives fail, or why 95 percent of New Year's resolutions are forgotten by February? The same reason traditional training methods have little impact on workplace behaviors, and why the "carrot and stick" (reward vs. punishment) approach to changing behaviors doesn't work. In this article, we detail how to really change your quality culture and improve GMP behaviors.

"Human behavior flows from three main sources: desire, emotion and knowledge" – Plato

To get you thinking, take this article to your next team meeting and ask colleagues these questions (we've provided our thoughts in italics):

1. Can you work any harder? Can you run any faster?

Most people we meet simply can't run any faster.

2. Imagine it's 5 p.m. on a Friday. Do you skip out of the office door buzzing with energy?

Finishing at 5 p.m. on Friday is a luxury for many. As for skipping out the door? I can hear you laughing from here.

3. Is your work-life balance good?

For a vast majority, the balance is firmly tilted towards work.

4. Do you believe in the old saying "If it ain't broke, don't fix it?" In other words, if

something appears to be working, leave it alone.

We believe that what worked in 2016 may not work in the future. Many regulations, systems, practices and behaviors are no longer fit for purpose. Maintaining the status quo is no longer good enough.

5. Do you think 2017 will be the same as 2016, business as usual?

Just look at the news. 2017 will not be the same. It will not be business as usual.

6. Does every day go to plan with no surprises?

Many we meet live in a world of surprises. Some have a dangerous addiction to fire fighting and crisis management.

Fact: 2017 WILL NOT be business as usual.

- > Pressure to make medicines more affordable will intensify
- > Price regulation will become the norm, even in the USA
- > Speed to marketplace must improve. Development pipelines will come under

intense pressure to make new medicines available faster

- > New science and technology must be embraced and implemented
- > Lots more new regulations to comply with? You bet!
- > The acute shortage of skilled and experienced people will start to bite hard
- > Uncertainty is here to stay. The unpredictable impact of political and socioeconomic changes, extreme weather conditions, urbanization and globalization will all have dramatic effects

Fact: When conditions change, so must our behaviors. You don't have to believe this; survival isn't compulsory.

Those who believe in the old saying 'if it isn't broken, don't fix it' are in for a really tough time

Now I'm a glass half full type of person. A born optimist in fact, and I strongly believe that if we embrace challenges then we can achieve prosperity:

- Challenges shatter status quo > **Adapt and improve**
- > **Retain right behaviors**
- > **Prosperity**

Remember, you can't change cultures without changing behaviors first

What Behaviors Must We Change?

To prosper in this unpredictable world, we, the pharmaceutical industry, **MUST**:

- > Move from rules-based **compliance to engagement**. Only engaged passionate people make things happen

- > **Stop training** people and educate them instead. *There's a difference. You train your pets but educate your children. People need to know the why, not just the how*
- > **Stop making the same mistakes** (repeat deviations)
- > **Stop blaming people** for errors and fix the systems that created them in the first place
- > **Get management away from meetings** and emails, and onto the shop floor where they add value
- > Replace our **addiction to firefighting** with one of continuous improvement
- > **Start using science (data)** and common sense to assess risk, not emotion and assumption
- > **Start doing less**, and excel at doing the basics to Ph.D. level
- > **Wage war on complexity**, removing everything that adds no value
- > Move from **CAPA (corrective focus) to PACA**. Prevention must become our priority
- > **Stop "death by measure"** and focus on what really matters
- > **Speed up decision making**
- > **Rebuild trust** with regulators. No trust = no relationship
- > **Put the patient** at the heart of everything

You probably have a few culture change initiatives along these lines already in process. But here's the scary part:

70 percent of change initiatives fail

Ref: MacKinsey & Co and Harvard Business Review



Changing Behaviors: What Doesn't Work

Focusing on Culture, Not Behaviors:

To change culture you must first change behaviors; not the other way around. Behavioral changes must be small. Big, top-down grandiose statements such as "This is how it's going to be" just don't work. However, focusing on changing small behaviors does.

The small behaviors that matter in reducing repeat problems are:

- > Ensuring **every** investigation takes place at the scene of the incident, not from behind a desk
- > Making sure **every** incident is risk ranked within 30 minutes
- > Completing investigations of minor incidents within four hours and majors within five working days
- > Ignoring the term root cause, and focusing on the error chain instead
- > Making sure 80 percent of actions are preventive (fixing the systems) and 20 percent corrective (immediate risk reduction)

Starting Big or Trying to Change Everything at Once:

When you have no sense of priority. When the goal is big, impersonal and imprecise (such as improving GMP standards), it will be forgotten in weeks. If you want success, focus on changing small behaviors first, such as a commitment to implementing and enforcing '5S' will have a more dramatic impact. It's precise, visual and personal.

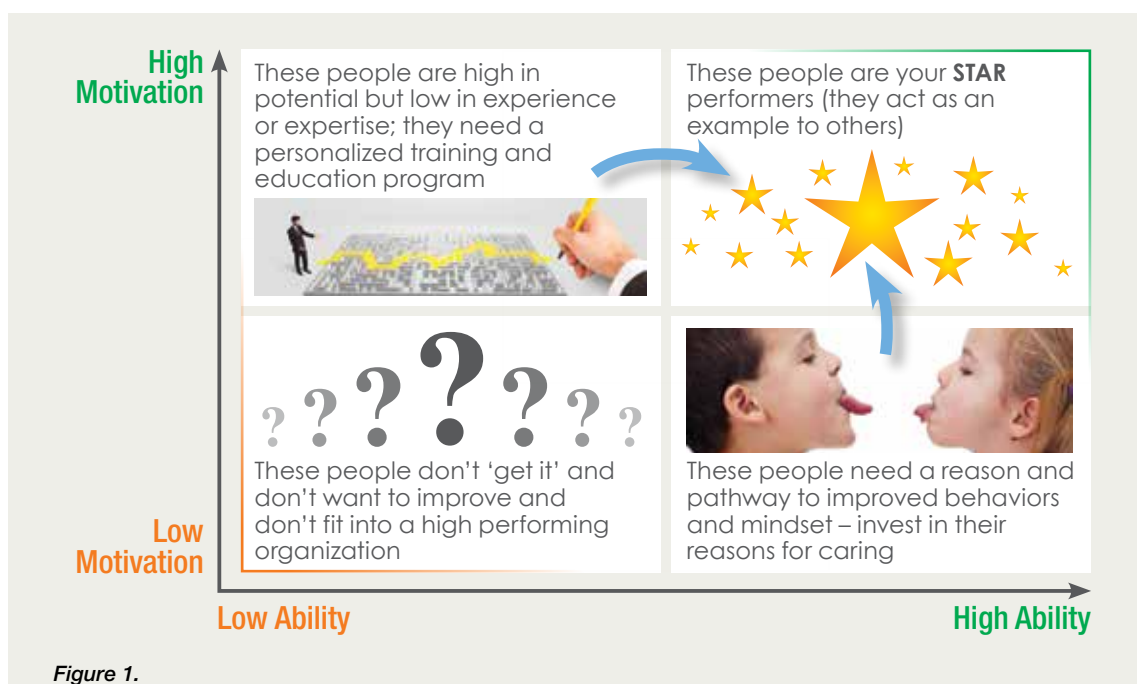
Likewise, don't waste time on improving SOP compliance as an initiative. It will fail. Focus instead on applying our rules of 'brutal thinking' (document simplification) and ensuring you have an FC readability score of 80-90. I will cover this on our course. www.nsf.org/training-education/training-entry/changing-gmp-behaviours-1864025

Trying to Stop an Old Behavior Rather Than Start a New One:

Behaviors and habits, over time, become hard-wired. They can't be removed, only replaced by stronger habits. The best way to do this is to focus on the new, not on stopping the old. Telling people to stop doing something only reinforces it.

Seeking a Result, Not a Ritual:

When you focus on a result and not the ritual (routine) you will not change behaviors. Remember the Toyota way where "the right process always



delivers the right results.” Committing to reading more books will soon be forgotten. Implementing a ritual (habit) of reading 20 pages a day stands a better chance of success.

Giving Up Too Soon:

Changing old behaviors (and eventually culture) is hard. We rely on habits to survive. They are ingrained. Most people expect immediate results and give up when they don’t happen. Even simple behaviors take weeks to change. Many months of focused effort are required to change complex habits. You have to stick with it.

Not Changing the Environment:

Behaviors are dramatically affected by the environment which includes systems, procedures and measures. Unless these change, old behaviors will quickly return.

Changing Behaviors: What Works

The Fogg Formula: B=MAth

BJ Fogg, a behavioral scientist at Stanford University, identified three components to behavior: motivation, ability and habit. We have added a fourth component that really helps us in Pharma – the trigger. So, to change any behavior you must:

- > Be intrinsically **m**otivated to do the right thing and know what the right thing is
- > Have the **a**bility to change. This means the new behavior must be simpler than the old one. It must take less effort (physical and mental) and less time, otherwise why bother? You must know in detail how and why change must happen.
- > The new behavior must then be practiced until it becomes a **h**abit that you do automatically. This involves having all of the components of the habit loop:
 - ◆ A **t**rigger. Something to remind you
 - ◆ A simple routine to follow
 - ◆ A reward that reinforces the new behavior

Different people have different needs – and our coaching and support needs to be customized

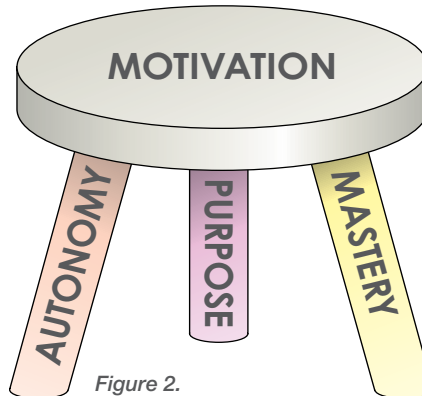


Figure 2.

to get the most from the people around us. (See Figure 1.) The reality is, however, for some people the disciplines and technology associated with pharma industry simply doesn’t jive with them. They may never fit within your high performing team.

Motivation

You can’t force anyone to do something they don’t want to do. People have to believe that the advantages (benefits and anticipated outcomes) of the new behavior outweigh the disadvantages of sticking with the old behavior. Changing any behavior is easy providing people are intrinsically motivated and the new behavior is simple.

True motivation is intrinsic. It’s personal, emotional and deep-seated. Intrinsic motivation requires autonomy, mastery and purpose (see figure 2.):

- > **Autonomy** (freedom) over the task:
 - ◆ Treat people as players, not pawns. When you hire good people, just leave them alone. Good people need freedom, not rigid instructions
 - ◆ Google employees have one day every week to work on something they choose. Half of Google’s new products and offerings come from this day of autonomy
 - ◆ Gallup’s extensive research on motivation in the U.S. shows 50 percent of employees are not engaged at work. In fact, nearly 20 percent are actively disengaged. The cost of disengagement? Gallup reckons about \$300 billion p.a.

- > **Mastery:** The desire to continuously improve at something that matters and to make a difference. Mastery is achieved by deliberate practice, repetition and constant, critical feedback
- > **Purpose** toward achieving a greater achievement beyond self or your company. A feeling of self-worth and contribution toward a greater good
 - ◆ The behavior must be consistent with their self-image and must not violate personal standards
 - ◆ The emotional reaction to performing the behavior must be more positive than negative, and must be more socially acceptable with peers than the old behavior

When it comes to motivation, timing is everything. As the old saying goes, “never let a good crisis go to waste”. A bad regulatory inspection, a product recall, warning letters and other big events are great opportunities to change behaviors and reboot habits. The more painful the event, the more effective the reboot.

Ability

The key to changing behavior is to make it so easy people just can't say no

Ability means:

- > Having the knowledge and context: the reasons **why**
- > Having the tools needed to perform the task: equipment, **simple** procedures and **simple** systems
- > Removing any barriers that prevent the adoption of the new behavior. Barriers can be tangible (time, money, old procedures and systems, equipment and plant) or psychological (anxiety, discomfort, peer pressure)

Triggers

We all need reminders, signals, indicators and aide-mémoires. We use them consciously (traffic lights) and unconsciously (hunger pains) every day. Help your staff develop the right habits by providing the right reminders, thoughtfully applied and at the right time and place.

Habit

A habit is formed when people perform the new task automatically. We are all creatures of habit when we act without consciously thinking. Driving to work, brushing your teeth, etc. In fact, 40 percent of the decisions we routinely make are habitual.

- > Habits are vital to our very survival. They free up valuable thinking time for the really important decisions
- > Habits are the product of pure repetition. The more we practice, the stronger the habit. The number of repetitions depends on the complexity and the person. The greatest gains come from the earliest repetitions. Dedicated practices in the first 20 hours is critical
- > Once formed habits can't be broken, simply replaced with a stronger habit
- > Under conditions of stress, the strongest habit rules supreme

Remember, brutal simplification usually precedes behavior change. The following references will help:



<http://www.nsf.org/info/pbwebinars>



<http://www.nsf.org/newsroom/nsf-pharma-journal-issue-36-2016>

A Behavioral Change Process That Works

NSF has developed a unique five-step behavioral change process that works, which we share in our training course:

Step One:

Identify the specific behavior you want to change using our simple diagnostic tools.

Step Two:

Understand what drives the old behavior. We will show you how to use the Klein process and other methods.

Step Three:

Get people motivated. We will show you how to assess and improve the three levels of motivation (autonomy, purpose, mastery).

Step Four:

Create the ability for the new behavior. You will practice some brutal thinking and other simplification tools and techniques.

Step Five:

Make the new behavior a habit. You will learn how to create memorable triggers, simple routines and rewards that reinforce the new behavior.

Your Call to Action

We have conducted many customized, in-house and residential courses for clients using this five-step process and our behavioral change tool kit. Significant improvements in SOP compliance, housekeeping and dress discipline, right-first-time and deviation investigations were all achieved.

Changing GMP Behaviors, 29-30 June, Manchester, UK – Presented by Martin Lush

If you want to succeed in changing behaviors and improve your quality culture, this course is a must!

You will leave with:

- > A detailed understanding of what drives behavior
- > A set of tools and techniques that you can use immediately to improve workplace behaviors
- > Access to free NSF resources and support to help achieve success in the workplace
- > The knowledge on how to change your own behaviors and habits
- > All your questions answered. Guaranteed.

Follow this link to register now www.nsfhumanerrorprevention.org

This course has achieved dramatic results we want to share these case studies with you.

Don't miss out!



So How Is NSF Moving E.A.S.T.?



by John Johnson,
Executive Director,
NSF Health
Sciences Pharma
Biotech Consulting

How does an organization stand out from the crowd in the global marketplace, where businesses vie for attention and custom, and a multitude of choices exist in every transaction?

The simple answer is that it must provide a differentiator; something authentic and valuable that is different from everyone else. Its novelty is often in its **simplicity** (for example the iPad), its **technology and performance** (like the Dyson vacuum cleaner) or its **sheer beauty** (like the offices at The Shard in London). The differentiator is what attracts us and grabs our attention when faced with a bewildering selection of similar choices.

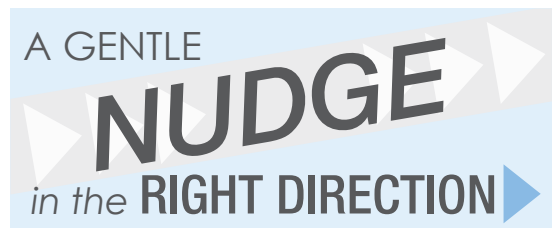
But that isn't enough to build a long-term interest in your product and services.

In order to be and remain the #1 choice, a business needs to develop a relationship with its clients, one that truly reflects the needs and values of the client. It needs to essentially build a community or set of shared experiences with the client which then affects its choices at a behavioral level. At NSF, this is at our very core and it is reflected in our values which shape our approach to working with you:

Our Core Beliefs

- 1) **Cultivate partners**, not clients
- 2) Be **sustainable**
- 3) Provide **education**, not training
- 4) **Plan** for the future
- 5) Challenge the status quo. **Think differently**
- 6) Ensure **return on investment**

In 2010, the UK government set up the Behavioral Insights Team to research the key drivers that influence behaviors, helping to ensure communications from the government positively influence the choices made by the general public.

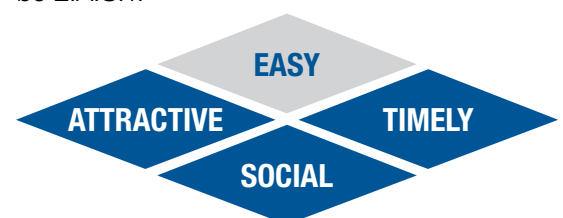


This team (often referred to as the “Nudge Unit”) has provided some guidance on how to change behaviors and choices; and NSF has been innovative in applying these tools within the GMP environment to actively influence the choices of pharma staff when faced with decisions in the grey zone.

We believe in three basic perceptions:

- > No one turns up for work actively looking to make errors or do a poor job
- > SOPs are generally written very poorly; they are not the most effective training aid and don't always enforce the right behaviors or decision-making
- > Education is more effective than merely training to SOPs and when human behaviors are considered as part of a continuing education program, the benefits to the organization can be exponential

The Behavioral Insights Team identified that, in order to make the right choices natural and the wrong choices difficult, any communication that seeks a change in an organization has to be E.A.S.T.



Easy. When designing a workplace or SOP, make it easy to do the right thing and remove all possible routes that lead to the wrong outcomes. Reduce human error or process variation by applying user-centered design right from the start to make error reduction a habitual, expected part of everyone's job. Make it natural by ensuring simplicity is at the core of every task in the work flow and by providing the right tools, reminders, checks and records.

Atttractive. Make the work simple and engaging. Allow staff to see the results of what they do immediately – everyone loves immediate feedback and we are attracted to tasks that provide an immediate sense of accomplishment and a sense of a job well done. Make sharing results interesting rather than a critique. Identify what your team finds attractive in their tasks (and do more of it) and change, eliminate or reduce the impact of the unattractive tasks where you can.

Social. People benefit from being in a team; we learn quicker and make new norms faster. Make it antisocial to be error prone or shoddy, make it attractive to be part of a winning team.

Timely. Pick your time for any communication, 'strike while the iron is hot' and be there when a problem or challenge surfaces. Having the right people at the right place at the right time is key to solving any issue.



We couldn't possibly help you to make your GMP processes E.A.S.T. if we didn't look at our own organization the same way, so here's an insight on how we are using the same tool:

E.A.S.T. What are we doing?

Easy	<ul style="list-style-type: none"> > Introducing an NSF app (watch this space!) > Evaluating and improving all of our client liaison processes > Simplifying our scope of works or proposal form > Improving access to our expertise via more webinars and YouTube videos
Attractive	<ul style="list-style-type: none"> > Improving our website > Using more videos, graphics and mindmaps to cut the number of slides in our courses
Social	<ul style="list-style-type: none"> > Our QP alumni group celebrated 30 years of NSF in 2016 > Our QP course continues to introduce new mentorship methods, pastoral care and support way beyond any other training course in the market > Our presence at conferences continues to grow including CDA, PQG and ISPE > Our input on LinkedIn and industry message boards continues to grow > Our offerings are customized so that they can be run in-house; bringing your team together to share one targeted learning experience
Timely	<ul style="list-style-type: none"> > Many of our courses now include e-reminders of the key learning objectives > Access to our expertise is being made easier, slotting into your busy schedules > We offer weekly news updates on the pharma biotech industry through our Daily Dose Digests

We use this in our business, and it works. How can you make sure your next project, SOP upgrade or GMP improvement is made easy, attractive, social and timely?

Expert Corner



by Anne Davies,
Client Project
Manager, NSF
Health Sciences
Pharma Biotech
Consulting

A common theme we discuss with our clients is the need to be sure that individuals know what they are expected to do. Poor, inappropriate actions, or just inactivity, can lead some people's managers and colleagues to believe that they are either incompetent or not aware of the expectations of their role. It could be that their role is not well defined or scoped. In these circumstances it is easy to see how things fall through the cracks.

Invariably, we find that education in the technical understanding of the business helps to change behavior; after all, our industry has never been better equipped with highly qualified and intelligent people. What we need is to provide context and breadth of understanding. Application will usually follow and with that appropriate behavior. To help clarify roles, I have been working with a number of clients on certifying key roles, and the results have been very positive. Feedback from the individuals has shown that they finally "get it" and working in the QA, manufacturing or QC environment is so much easier and rewarding.

Role Definition

The GMP regulation on this subject can seem quite vague, but really finding out what is required for a role is not so complicated. There

are drivers such as SOPs, company values and role responsibilities, and these can be broken down into a training matrix for the role.

Then we need to look at how to structure a certification or qualification process. I have found that this needs to be structured and broken down with key roles identified. Here is a typical flow of activities leading to good learning processes and ultimately individuals who understand their role and how to behave. (See figure 1.)

The Stages

The educational element is where you provide the context. No matter how qualified your graduates are when they enter your system, they are at best naive and at worst dangerous when let loose on pharmaceutical processes. Ensure they get the best educators and that this education is broad and all-encompassing for the role – it will pay dividends in the short term and compound interest in the long term as they progress through your company to become decision makers of the future.

The SOP theory is very company-based and should cover what recent recruits need for the job, focusing on the areas of real interest to their role. Do not be tempted to swamp them with everything all at once, as they will get to know the nuts and bolts of your business over time. Initially, they just need to know their role and their responsibilities. Use an experienced person to guide them through this process, who can help with the background and answer

So what is expected for the individual?

Each job to have a job description

- > Role description
- > Requirements of the job
- > Some companies have targets but this is unusual

Training Matrix or Plan per individual

- > Compliance training
- > Education requirements to perform
- > Record of performance/tracking of completion

What is Certification?

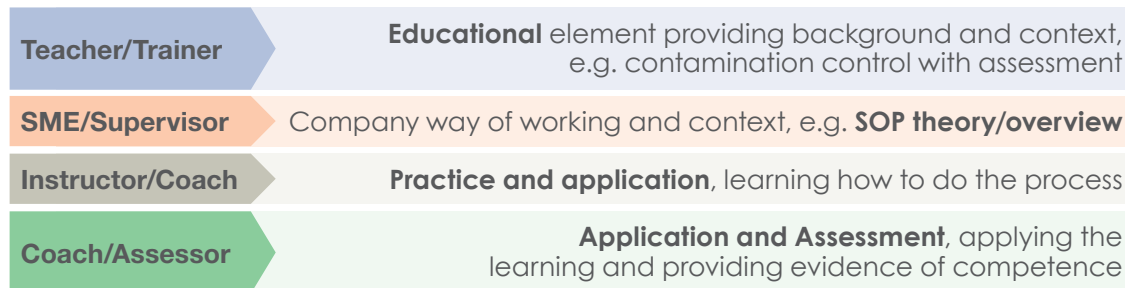


Figure 1.

questions and queries. With the contextual element covered already, they will review this process from an enlightened point of view of logic and it could start to provide that light bulb moment.

Over time they will need to apply these two elements to their day-to-day activities and you will need a coach or instructor who has experienced these activities and who is a good practitioner as you want good habits forming. This process should not be rushed either; there is no fail, just time to get it right and learn from mistakes.

Assessment needs to be in a positive environment linked to proficient testing, feedback and coaching throughout the process.

This overall process works well for most roles, and can be adapted to allow for an individual's pre-qualification or experience. I have found that with mentoring, feedback, and experience dealing with problems, people gain confidence in taking action and are better able to defend positions and challenge and change poor situations.

What Roles?

Some of the typical roles I have recently worked with have been surprising. The figure shows an example of the roles and the content of education that has been applied, some by NSF and some by internal training. (See figure 2.)

These might not be what most people expect with certification programs, but they have all made sense. In the QC microbiologist example, our client was working with sterile products and during investigations the QC micro laboratory was called on to provide extra testing and results. They were not consulted or used in the investigation team. By increasing their breadth of knowledge in the way indicated they were able to help with contamination control in manufacturing. By joining the investigation team with a part to play in problem solving, the micro lab team members were able to add their unique knowledge to the solution finding, gaining renewed confidence and understanding of the practical challenges of the production area.

Suggested Certification content

Batch Release/Review	QC Microbiologist	Deviation Champions	Internal Auditor
> QMS	> QMS	> QMS	> QMS
> Pharma GMP	> Pharma GMP	> Pharma GMP	> Pharma GMP
> Applicable Product Manufacture	> Applicable Product Manufacture	> Applicable Product Manufacture	> Applicable Product Manufacture
> Analysis & Testing	> Pharma Micro	> Investigation Techniques	> Pharma Packaging
> Pharma Packaging	> RBDM	> RBDM	> Auditor skills
> RBDM			
> Pharma Law & Admin			

Figure 2.



by Howard Broadbridge, Business Development Manager, NSF Health Sciences Medical Devices

The Quality Professional's Career Path: New Challenges and Opportunities

The medical device industry is currently undergoing significant change. Steady growth in the industry – fueled by a combination of increasing demand for high quality healthcare, globalization and innovations in treatment – has resulted in a shortage of quality specialists and a clear competency gap.

A side effect of this is also evident among European notified bodies, contract manufacturers, IVD manufacturers and consulting companies, which now see vacancies for high caliber quality professionals at record levels. Notified bodies are now investing heavily in recruitment and are training more regulatory and technical people in order to address current demand.

The situation has been compounded by recent public health scares such as that triggered by the PIP scandal, which have led to an increase in notified body scrutiny and unannounced audits. The new European medical device regulations, which are currently being translated into 24 languages in preparation for final approval from the European Council in Q1, 2017, will also significantly increase the workload for the quality function.

Unsurprisingly, the demand for excellent QA/RA specialists has never been so high, with industry losing staff to notified bodies

and individuals offering their services as independent consultants. Companies are also beginning to realize that a shortage of regulatory compliance professionals will adversely affect their ability to attain or retain product approval in Europe.

Whereas all this presents considerable opportunities for quality professionals, competition for the best-paying jobs will still be keen, and those with the most relevant qualifications and experience will succeed. The earning potential of candidates and their trajectory of advancement will depend on their starting point (graduate or non-graduate) and on the subsequent qualifications they achieve.

Benefits for Employers

Employers, and specifically HR departments, recognize the need to retain good people and the long-term benefit of having the best qualified staff in the quality function. Inevitably, a constant focus on total quality will filter



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through to more reliable products, fewer complaints, more satisfied customers and, ultimately, increased revenues. Having the most knowledgeable quality managers will also reduce instances of non-compliance, resultant inspections and interruptions to production.

Postgraduate qualifications that challenge employees in subjects relevant to their work both add value and lead to successful recruitment, retention and career development.

Professional training in QA/RA is therefore essential for those wishing to maximize their income and fill the best roles. NSF Health Sciences offers a range of training courses covering areas such as design history, risk management, auditing skills and dealing with notified bodies and regulatory authorities. The courses are delivered by experienced tutors who are usually leaders in their field of expertise. To provide flexibility, they are run as part of a public training schedule or can be tailored to company requirements and delivered in-house.

In summary, the changes in the medical device regulatory framework are going to hit harder than many appreciate – and much earlier. Well-qualified QA/RA managers will be in high demand and harder to find. Medical device and IVD companies should prepare for the impact now by thinking strategically, putting plans in place and budgeting to recruit and retain excellent managers.



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We are looking for an Associate Director and Associates

We are looking for an Associate Director of Pharma Biotech Consulting to join our busy Kirkbymoorside office in the UK. This position provides an exciting opportunity to grow into a senior leadership and management position within the company.

Contact **Mike Halliday** at mikehalliday@nsf.org for more information on this position.

We are also looking to add some talented people to our European associate team and John Johnson would be glad to explain our vision and immediate needs. Contact **John Johnson** at johnjohnson@nsf.org





by John Johnson,
Executive Director,
NSF Health
Sciences Pharma
Biotech Consulting

Summary of Anticipated Changes to Annex 1 EU GMP Vol IV

Origin of the Changes	Andy Hopkins (MHRA) along with a Joint EMA PIC/S Working Party
Timeline	<ul style="list-style-type: none"> > Draft concept paper issued by MHRA to EMA Inspection Working Group (IWG): September 2014 > Full draft issued to EMA IWG: Second quarter, 2016 > Concept paper to be published: January or February 2017
Reason for Change	<ul style="list-style-type: none"> > Alignment of Annex 1 with current industry expectations and technologies > Clarification of some key requirements > First major review since inception in 1996 > Alignment to ICH Q9 & Q10 > New/emerging sterile manufacturing entities require additional detail
Key Quote	<p><i>"No adverse impact on industry with respect to either resources or costs is foreseen."</i> – Andy Hopkins</p> <ul style="list-style-type: none"> > NSF would add that this of course depends on the level of CGMP compliance in place at your facility at present. When regulations change, how do you respond and how do staff behaviors affect your ability to embed the changes?

3. General

- > Eliminates contradictions

2. Principles

- > Reinforces existing GMP requirements

1. Scope

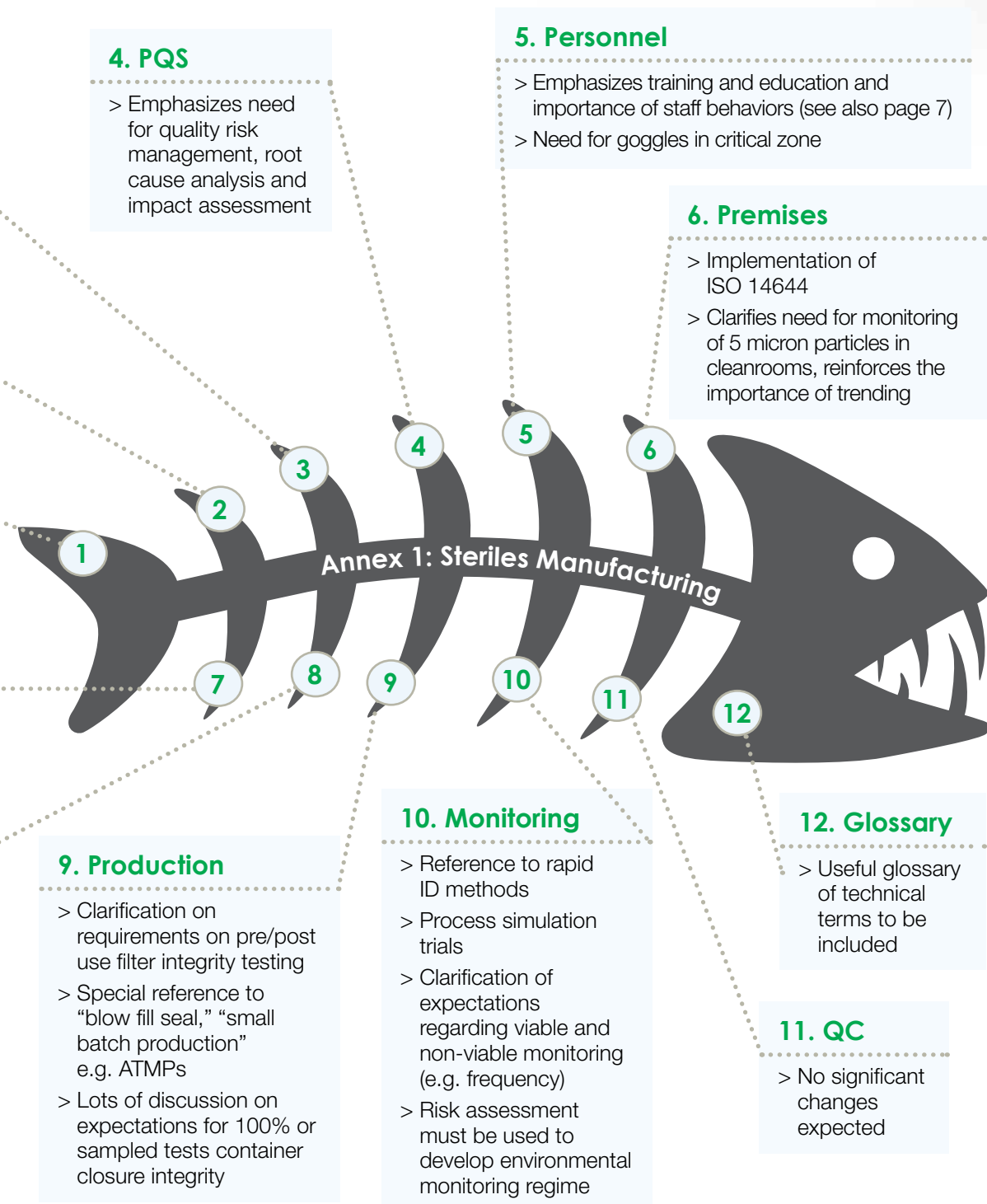
- > Provides links to other related parts of GMP e.g. 2003/94 Article 5, 2001/83 Article 23, Chapter 3, Chapter 5.10

7. Equipment

- > Emphasizes need to separate operators from process using RABs and isolators

8. Utilities

- > Requirements for compressed air, prevention and removal of biofilms in water systems
- > Generation of WFI will align with Ph. Eur. i.e. use of reverse osmosis will be permitted



For more information, get in touch at johnjohnson@nsf.org and watch out for our webinars at www.nsf.org/training-education/all-courses/category/pharma-training

Regulatory Update



by Pete Gough,
Executive Director,
NSF Health
Sciences Pharma
Biotech Consulting

Paradigm Shift Planned in the Relationship Between U.S. FDA and the European Medicines Agency

By Pete Gough

Mutual recognition of inspections on the way?

It has been reported that negotiations for an EU-USA mutual recognition (of inspection) agreement (MRI) have progressed to the point where the agreement is expected to be completed in early 2017. There are still some points to be resolved around the sharing of confidential information but there is now an air of optimism that a final agreement is achievable. Negotiations on an EU MRI with the USA started in the late 1990s so this has been a protracted process that may finally reach a successful conclusion.

If an MRI is reached with the USA, the FDA would accept EU regulatory authority inspection reports and no longer inspect in Europe and vice versa. It may even lead to the FDA and EMA accepting each other's inspections of third countries, which would significantly reduce the burden of inspections for both agencies.

This will have huge implications for the industry and will create a significant range of opportunities and challenges across the sector.

PIC/S Expands Membership With Five Additional Applicants Being Assessed and Further Harmonization Planned in 2017

The Pharmaceutical Inspection Co-operation Scheme (PIC/S) has now expanded to 49 members with Thailand's Food and Drug Administration (Thai FDA) joining the scheme on August 1, 2016. Five additional applicants are currently being assessed:

- > Brazil – ANVISA
- > Iran – IFDA
- > Mexico – COFEPRIS
- > Philippines – PFDA
- > Turkey – TMMDA

The PIC/S Inspectorates' Academy (PIA) is now up and running.

The PIA is a PIC/S initiative to set up a web-based educational center under the PIC/S umbrella for harmonizing and standardizing GMP training at an international level through a certified qualification system. PIA delivers not only general or advanced training, but also serves as a platform for discussion and sharing among regulators. It offers a single point of access to all PIC/S training activities and is being implemented in various stages.

PIC/S has a number of working groups (WG) who are developing guidance for inspectors and, in some cases, for industry; the current WGs are as follows:

- > Data Integrity
- > Harmonization of Classification of Deficiencies
- > The EMA (European Medicines Agency) – PIC/S Joint Drafting Group on the revision of Annex 1 (sterile manufacturing)
- > Controlling Cross-Contamination in Shared Facilities
- > Good Clinical Practices (GCP) and Good Pharmacovigilance Practices (GVP)
- > Veterinary Medicinal Products
- > Site Master Files
- > Advance Therapy Medicinal Products
- > Validation Master Plan; Installation and Operational Qualification; Non-Sterile Process Validation; and Cleaning Validation
- > API Q&A developed by PIC/S, which were not transferred to ICH



Glidepath for Brexit announced; No Immediate Regulatory Changes Needed

The UK Prime Minister has indicated that the UK government will trigger Article 50 of the EU Treaty, which formally starts the process for the UK to exit the EU, by the end of March 2017. As this should be a two-year process (unless all Member States agree to an extension), this would result in the UK formally leaving the EU by March 2019. Nothing formally changes until this date.

It is expected that the UK government will bring forward a Bill in Parliament to repeal the 1972 European Communities Act and that this act will take all of the existing Statutory Instruments (including SI 1916-2012, which implements most UK medicinal products law) issued under the 1972 Act and bring them into force under the authority of the repealing Act. This will mean that initially nothing will change in UK law. The government will then be able to modify existing laws gradually over the next several years; a process that could continue for a decade or more.

New Guidelines From U.S. FDA

By Andrew Papas

ANDA Submissions – Prior Approval Supplements [for Generic Drugs] Under GDUFA

FDA released a guidance in October 2016 intended to assist applicants preparing to submit to FDA prior approval supplements (PASs) and amendments to PASs for abbreviated new drug applications (ANDAs) under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)). The guidance explains how the Generic Drug User Fee Amendments of 2012 (GDUFA) relates to PAS submissions. The guidance also describes the performance metric goals

outlined in the GDUFA Commitment Letter that FDA has agreed to meet, and clarifies how FDA will handle a PAS, and amendments to a PAS for an ANDA subject to the GDUFA performance metric goals. In general, a PAS that requires an inspection will have a 10-month review clock and a PAS not requiring an inspection will have a 6-month review clock. Amendments to the PAS are expected to be rare and, if submitted, may extend/reset the GDUFA clock.

Impact of Failure to Self-Identify Generic Drug Facilities

Under GDUFA, human generic drug facilities, sites and organizations are required to submit identification information electronically to FDA annually. FDA recently issued the guidance Self-Identification of Generic Drug Facilities, Sites, and Organizations Guidance for Industry to help human generic drug facilities, sites and organizations meet the self-identification requirement. FDA uses the site registrations to identify the generic global supply chain.

Most facilities that self-identify are required to pay an annual facility user fee. These include facilities manufacturing, or intending to manufacture, APIs of human generic drugs and/or finished dosage form (FDF) human generic drugs.

Facilities that fail to self-identify create a risk to themselves and to their clients. While GDUFA provides no explicit financial penalty for sites and organizations that fail to comply with the self-identification requirement, if a facility fails to self-identify, all FDF or API products manufactured at the facility, and all FDFs containing APIs manufactured at the facility, will be deemed misbranded. It is a violation of federal law to ship misbranded products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions or seizures of the misbranded products.



by Andrew Papas,
Vice President
of Regulatory
Affairs, NSF Health
Sciences Pharma
Biotech Consulting

Associate Spotlight: **Getting to Know Roger Guest**



Our team prides itself on its people, and our cadre of expert associates takes center stage when we are tasked with an enquiry from a potential client. We know our

team is the best, but who are they and what are their particular insights into the pharma industry? **John Johnson met with one of our associates, Roger Guest, Ph.D., MRPharmS, and asked him about working with us.** Roger is a registered pharmacist who has held senior leadership roles in R&D, manufacturing and QA with several blue chip pharmaceutical and biotechnology companies in Europe and the U.S.

Roger, what gives you a buzz from working with us?

“It’s the camaraderie of working in a team, within a knowledge base that has ‘been there and done it’, yet is open-minded and alive to future challenges. As a team we feed off each other, making sure clients get the most proportionate and practical advice available.”

What are these future challenges, and where do you see the industry going?

“When global supply chains become so complex and diffuse, management oversight and chain of command become incredibly difficult. Management of a network relies on highly engaged people who take active responsibility for their own knowledge, who can quickly understand when a scenario is emerging and can then select the right actions to take. Education and knowledge management of key staff will determine whether the right choices are made.”

How is this different from the past?

“In many ways it isn’t; it’s just the industry is now faster-paced and more competitive than ever. What worked OK previously, often doesn’t work so well any more. With a propensity for ‘silo thinking’ and with a multitude of specialists, making joined-up decisions is harder than ever.”

So what was the toughest place that you ever found yourself in, Roger?

“Until you have experienced it yourself, people don’t realize how spectacularly difficult it is to rebuild trust after a regulator takes action to ensure GMP deficiencies are remediated. It is expensive, painful and time-consuming; many businesses are changed forever as a result of a regulator’s injunction or warning letter. In one role I had, after more than 12 months of hard work and more than \$12 m direct costs, the final decision on resumption of supply rested on a six-week FDA inspection. Now that was pressure!”

So what makes the difference? What differentiates successful companies from those that are effectively “dancing on the trap door”?

“The best organizations recognize that in a global marketplace, business and quality risks have to be actively sought out, studied and mitigated. Being able to oversee a network requires excellence in management review, staff development and communication. Being able to recognize ‘brutal reality’ (however unattractive) is the first step in tackling it for the better. It’s about realism and shrinking the unknowns.”

NSF relies on our expert associates, like Roger, and we are always looking for new high-caliber colleagues; especially in the steriles and biotech areas. If you have what it takes or can recommend someone, contact me at **johnjohnson@nsf.org** in confidence. If you are the best, you’ll feel at home with us.



NSF center stage at PDA/FDA Joint Regulatory Conference

NSF Pharma Biotech Consulting held center stage at the PDA/FDA Joint Regulatory Conference in Washington D.C. on September 12-14, 2016.



“NSF has a great relationship with PDA/FDA and always looks forward to exhibiting at this pivotal conference. It gives us a great opportunity to re-connect with clients, meet with the FDA and network with industry leading executives,” said Maxine Fritz, Executive Vice President of NSF Pharma Biotech Consulting.

This year’s show was highly attended with over 500 executives from countries around the globe. In addition to showcasing our remediation, training, consulting and auditing services, Martin Lush, President of NSF Health Sciences, gave an enlightening presentation on human error prevention. During this interactive presentation, Martin left attendees with simple, best-in-class steps on how to reduce human error.

If you are interested in learning more about this year’s conference and the relevant topics and trends discussed and how they will affect your business, including Martin’s presentation, contact him at martinlush@nsf.org

By Kevin Schimmel

Staff Updates Office

Aimee Harding and Bethany Thompson Join the Office Services Team



Aimee Harding

At the NSF office in Kirkbymoorside we are expanding our office services and further driving continuous improvement across all we do. As a result we have taken on new team members in these key client service roles. We are thrilled to announce that in August, Aimee Harding and Bethany Thompson



Bethany Thompson

joined our Office Services team. They both bring new perspectives and skills, in addition to their great enthusiasm which already makes them great assets to the team.

Stella Pearson-Smith Promoted to Office Manager



Many of you who have dealt with NSF’s team in Kirkbymoorside, and certainly most of our QP alumni, will know Stella. We are pleased to announce that Stella has been appointed to the role of Office Manager. Stella will bring her years of experience and her drive for excellence in customer service to this key leadership role. She continues to act as QP administrator and coordinator of our public training courses.

Data Integrity Assessment Tool



Do you have a data integrity issue? Find it, fix it and prevent it. Visit http://info.nsf.org/extranet/data_integrity/ and try our data integrity readiness assessment tool! This brief questionnaire will highlight aspects for companies to consider in relation to company-wide data governance systems to ensure proactive management for data integrity risks. It also identifies where and how NSF Health Sciences can be of help in supporting your company.

Forthcoming Courses

What's planned for January to July 2017

Pharmaceutical Formulation & Processing, Part 1

January 16-20, 2017

York, UK

Course Fee: £3395 excl. VAT



Pharmaceutical Legislation Update: Continuing Professional Development for Qualified Persons & Technical Personnel

March 22, 2017

Manchester, UK

Course Fee: £770 excl. VAT



GMP for Biological and Biotechnology Products

February 28 – March 3, 2017

Manchester, UK

Course Fee: £2300 excl. VAT

Pharmaceutical Formulation & Processing, Part 2

March 6-10, 2017

York, UK

Course Fee: £3395 excl. VAT



Pharmaceutical GMP Audits and Self-Inspections

(An IRCA Certified Pharmaceutical QMS Auditor/Lead Auditor Course)

March 27-31, 2017

Manchester, UK

Course Fee: £2880 excl. VAT



A – Z of Sterile Products Manufacture

March 13-17, 2017

Manchester, UK

Course Fee: £3000 excl. VAT



Quality Management Systems

April 3-7, 2017

York, UK

Course Fee: £3395 excl. VAT



Pharmaceutical GMP

March 20-23, 2017

Amsterdam, Netherlands

Course Fee: £2300 excl. VAT



Pharmaceutical Microbiology

May 15-19, 2017

York, UK

Course Fee: £3395 excl. VAT



Techniques for Effective Failure Investigation

March 21-22, 2017

Amsterdam, Netherlands

Course Fee: £1540 excl. VAT

Free QP Seminar for Prospective QPs and Sponsors

May 16, 2017

York, UK

Course Fee: FREE

For more information, email pharmacourses@nsf.org or visit www.nsf.org/info/pharma-training

Course details are correct at the time of printing and are published in good faith. NSF reserves the right to make any changes which may become necessary.



The right people. The right solution. The first time.™

Pharmaceutical GMP Audits and Self-Inspections

(An IRCA Certified Pharmaceutical QMS Auditor/Lead Auditor Course)

May 22-26, 2017

Manchester, UK

Course Fee: £2880 excl. VAT



Pharmaceutical GMP

June 19-22, 2017

Manchester, UK

Course Fee: £2300 excl. VAT

Data Integrity and Governance Systems

May 23, 2017

Manchester, UK

Course Fee: £770 excl. VAT

Techniques for Effective Failure Investigation for Sterile Products

June 19-22, 2017

York, UK

Course Fee: £2300 excl. VAT

Data Integrity in QC Chemical Laboratories

May 24-25, 2017

Manchester, UK

Course Fee: £1540 excl. VAT

A – Z of Sterile Products Manufacture

June 26-30, 2017

Manchester, UK

Course Fee: £3000 excl. VAT



Active Pharmaceutical Ingredients

June 12-16, 2017

Newcastle upon Tyne, UK

Course Fee: £2880 excl. VAT



Changing GMP Behaviours

June 29-30, 2017

Manchester, UK

Course Fee: £1540 excl. VAT

The Role & Professional Duties of the Qualified Person

July 17-20, 2017

York, UK

Course Fee: £2750 excl. VAT



Effective and Efficient Process Validation: The Science and Risk-Based Approach

June 13-15, 2017

Manchester, UK

Course Fee: £2000 excl. VAT

NSF has gained Royal Society of Chemistry approval for courses marked with the logo as suitable for their members' continuing professional development.

Early Bird or Multiple Delegate discounts apply to some of our courses. Please visit our website, www.nsf.org for full details.

A full, up-to-date course listing is available online. Book your place at www.nsf.org/info/pharma-training



Simplification and Improvement of a Change Control System

What we found

- > A 56-page change control SOP that no one understood
- > Change requests that took 12–16 weeks to approve
- > Workarounds (some dangerous) and unofficial shortcuts
- > CC system that approved everything
- > Approvals based on gut feel
- > An eight-person CC committee remotely reviewing change requests
- > No follow-up of approved changes to measure success
- > No control over routine changes

What we left after NSF simplification

- > SOP reduced to seven pages
- > Approval time reduced from months to 60 minutes
- > No more workarounds and short-cuts
- > CC system rejecting 38–40 percent of change requests
- > Customized impact assessment forms to make decisions objective and business focused

Steps taken

- > Gap analysis of the CC system vs. best industry practice
- > A two-day, distraction-free workshop with all key stakeholders delivered to 25 participants to simplify the SOP
- > Core purpose of the CC system agreed to focus on speed and importance of objective decision making
- > CC system and unofficial systems process mapped
- > Non-value-adding steps removed
- > Customized impact assessment forms generated
- > Three CC members meet weekly to make decisions
- > Agenda of the CC clinic simplified
- > All approved changes followed up to assess ROI



Tools used

- > Gap analysis
- > Process mapping
- > Brutal thinking
- > Risk assessment
- > Customized impact assessment

Return on investment

- > Everyone slept easier at night knowing they had control over routine changes
- > Only changes delivering value were approved, dramatically reducing initiative overload and freeing resources

Behavior changed

People recognized that the CC system was vital to the health of their business and was not just about compliance.

Key message

Simplification motivates and inspires. People went from loathing (and ignoring) the CC system to loving and using it.

The right people. The right solution. The first time.™



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