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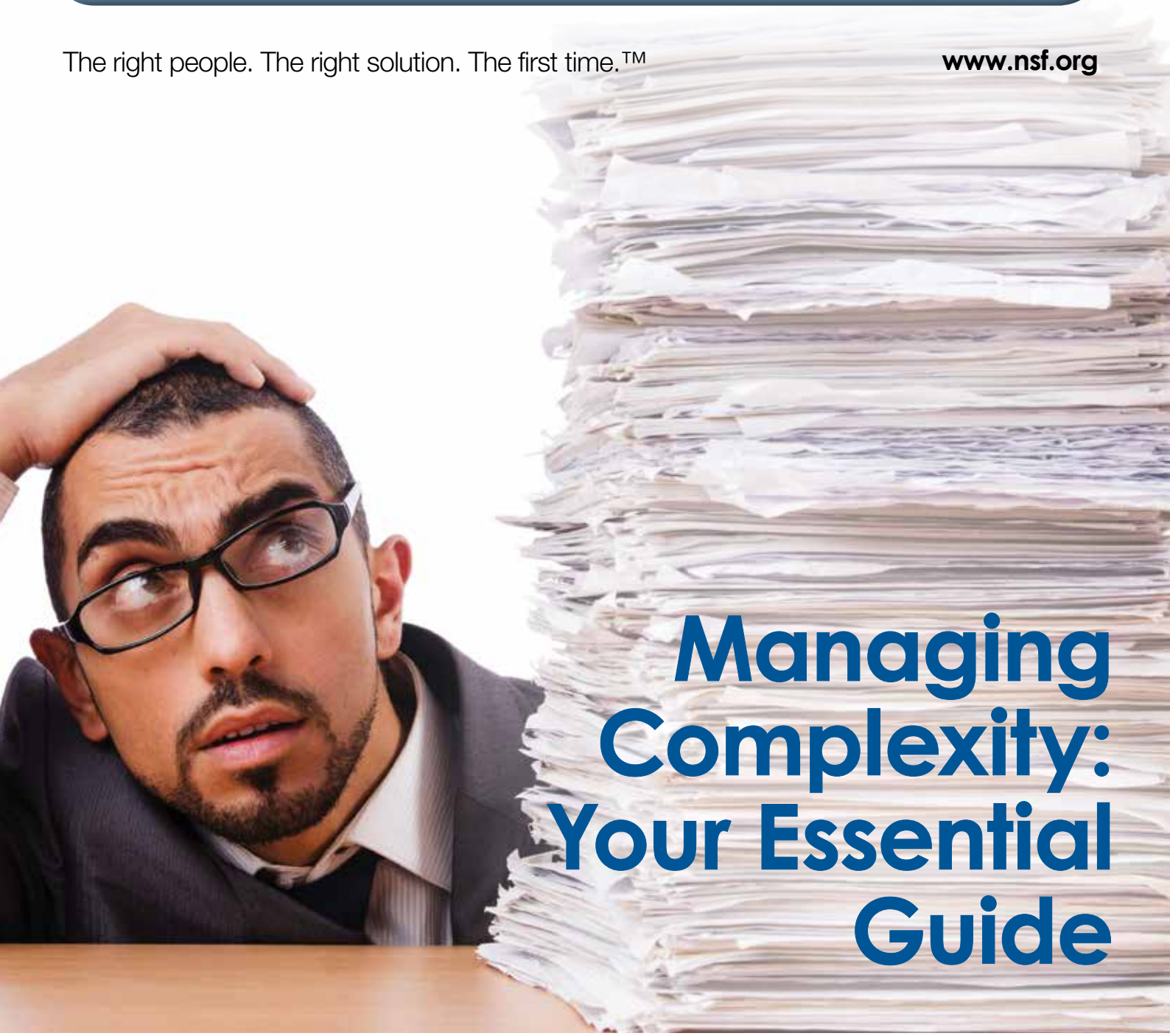

Managing Complexity: Your Essential Guide

NSF® Health Sciences Pharma Biotech Consulting

30 YEARS

30 Years of Patient Protection

welcome

Are You Suffering From "Excess Baggage"?

The focus of this edition is simple – to provide you with some ***simple*** **tools, techniques and ways of thinking to ELIMINATE THE UNNECESSARY**. If you want to reduce the complexity of your quality management system or are interested in drastically simplifying your documentation system, including SOPs and batch records, we provide some answers. Want a simple new product introduction process? We will show you how.

In the chaotic and unpredictable world we all live in, success awaits those who are capable of doing more with less. Complexity is your enemy. Talking of complexity, you will find Pete Gough's assessment of Brexit and its implications invaluable. So, if you are serious about a simpler and less stressful life, immerse yourself in this edition. Please contact us for more information and free resources on the art and science of simplification. As our case studies illustrate, we can help you.

We hope you enjoy this simple edition!

Martin Lush

Martin Lush, President, NSF Health Sciences Pharma Biotech Consulting

NSF Health Sciences Pharma Biotech Consulting

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ARE YOU FACING A COMPLEXITY CRISIS?

I spend a lot of time in bland hotels and rarely remember any of them… except one. This particular hotel will, forever, remain etched on my mind because of the complexity of its toilets. Now, most toilets are simple and straightforward with all the usual features in usual places. Not this one. This model came with a three-page instruction manual describing various power jets, temperature and "vibration" settings. I immediately did a risk assessment. Severity of harm? High. Probability of harm occurring? Off the scale. My conclusion? Ignore the gizmos and go for the manual override.

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

The experience reminded me of the challenges facing us all every day, unnecessary over-complexity.

Over the last 30 years my colleagues and I have seen levels of complexity in the pharma industry increase dramatically. It's getting close to a crisis point. Although some complexity is triggered by events we can't influence (regulations, globalization and the like), most is created by choice.

OVER-COMPLEXITY: THE COSTS

I was with a client recently following a tough GMP inspection. Their long and expensive Form 483 from FDA included all the usual "failure to follow SOPs", "repeat deviations", "multiple documentation errors", "data integrity issues" and lots more. Following the company's internal review, the site director provided me with a list of root causes and their even bigger, more expensive list of Corrective and Preventive Actions (CAPAs). He asked me what I thought, so I told him:

"These CAPAs will only make the situation worse because you've missed the single biggest cause of each and every regulatory criticism – OVER-COMPLEXITY."

OVER-COMPLEXITY: ROOT CAUSES

Your Self-Assessment Questionnaire

I firmly believe over-complexity is a silent killer for many companies. Most people know (and complain) about it but do little to minimize the dangers and risks.

Remember, complexity increases over time to such an extent that people just get used to it. Successful simplification only happens if you provide the reassurance that it will benefit those involved. If you do not, your attempts to simplify will be sabotaged.

Whenever we help companies following a tough inspection, we are interested in one thing: making sure they bounce back stronger by fixing the underlying cause, which is usually complexity.

Your Task:

Over the last 30 years we've identified the symptoms of over-complexity that lead to regulatory action.

> Discuss the eight symptoms listed on the next page with your colleagues over a cup of coffee
> Answer each with a yes or no
> Any yes's means you have a level of over-complexity that could prove risky

Don't Worry

> This edition of the Journal provides simple rules and guidelines to reduce risk by removing its cause – COMPLEXITY

Continued

ARE YOU FACING A **COMPLEXITY CRISIS?**

Symptom 1: Risk Aversion and a Focus on Risk Assessment, Not Risk Management

Yes ☐ / **No** ☐

Are you risk-averse? Do you focus on reactive risk assessment rather than proactive risk management where data and common sense rule?

Remember: Risk aversion drives a "more is better" mindset; more checks and measures, more detail in SOPs, more environmental monitoring, more everything. This is not surprising; most people are wired to want more. More is safety. More is less risk. But the opposite is true. Risk aversion drives the "pursuit of more" which increases risk.

Symptom 2: Poor Knowledge of Products and Processes

Yes ☐ / **No** ☐

Is there a lack of detailed knowledge of your products and processes across your organization? Unless there is deep understanding of every product's key quality attributes and process critical control points, attempts to simplify are dangerous.

Remember: Simplification is about understanding what's essential and what's not. Simplification is about focusing on the former and ruthlessly eliminating the latter. To simplify you must be brutal; you have to keep the essential and jettison the rest. This can't be done without in-depth knowledge.

Symptom 3: Organizational Bureaucracy and Complex Hierarchy

Yes ☐ / **No** ☐

Complex organizations are always at risk. Hierarchy and bureaucracy distracts and demotivates.

Remember: If you have any of the following you could be in trouble.

> Very busy but ineffective people
> A closed, blame culture
> Interdepartmental conflicts
> Lots of KPIs and measures
> Slow and ponderous decision making
> Poor morale and engagement
> Drawn-out sign-off and approval processes
> Lots of activity but not much change

Symptom 4: Corporate Rules

Yes ☐ / **No** ☐

Do your corporate colleagues issue rules and guidelines without user consultation and engagement?

Remember: Although well-intentioned, rules and guidance written without user involvement will always add complexity and risk.

Symptom 5: Unworkable SOPs and Documentation

Yes ☐ / **No** ☐

Most SOPs are so complicated they are impossible to understand and follow. Symptoms 1 to 4 lead to an epidemic of over-explaining in the mistaken belief that more information means greater clarity.

Remember: The opposite is true. More information leads to confusion and fuzziness. The **simplicity paradox** holds true. *"The less you tell educated people, the more they know."*

Symptom 6: The Firefighting Habit — Yes ☐ / No ☐

Do you struggle with large numbers of repeat deviations or human error incidents? Do many of your CAPAs recommend retraining, extra checks or more detailed instructions?

Remember: If you are addicted to firefighting and obsessed with the quick fix, the complexity created will turn the embers into infernos.

Symptom 7: Poor Change Management System – Initiative Overload — Yes ☐ / No ☐

Does your change control system approve every change request? If it does, it's creating complexity.

Remember: Your change control system is where "brutal thinking" is practiced. It's where changes that add complexity are rejected and those that simplify are applauded and approved.

Symptom 8: Bad Consultants — Yes ☐ / No ☐

Ever experienced consultants and third parties who just add "stuff" without understanding your needs? Do they use a one-size-fits-all approach?

Remember: Good consultants leave you more resilient and efficient. Good consultants simplify, bad consultants complicate and confuse. Time for some brutal thinking followed by action! Get rid of the bad, keep the good.

SOLUTIONS: MOVING FROM COMPLEX TO SIMPLE

If you want to simplify, remember:

> **Simplification is hard work.** It must be actively pursued. Making things complicated is the easy way out and symptomatic of lazy thinking and a wasteful organization

> Simplification requires **TOTAL dedication to clarity, honesty, discipline and intelligence**

> **Less IS more**

> **Be brutal.** Simplification is about understanding what's essential and what's not, focusing on the former and ruthlessly eliminating the latter

> **Excel at saying NO!** Simplification is about focusing on the essentials. Focusing is about saying no, no, no…

> **You don't have a choice!** Simplify or suffer

Remember, complexity leads to:

- More time needed when you have less available
- More cost you can no longer afford
- More energy wasted
- Greater risk
- Demotivation and disengagement

And finally, make sense and simplification your mantra. Simplicity is an exact medium between too little and too much. That's your goal.

SOME SIMPLIFICATION RULES

Throughout this Journal we describe how we've helped clients simplify:

> SOPs

> Batch manufacturing records

> Deviation and CAPA systems

> New product introductions

> Vendor assurance

If you would like more information on how these were achieved and the processes we used, drop us a line at pharmamail@nsf.org

Continued

ARE YOU FACING A **COMPLEXITY CRISIS?**

When simplifying, here are some common steps to consider:

Step One: Get the Basics in Place First

> Make sure you **have an open and transparent culture.** Simplicity only thrives in an open culture

> Make sure everyone understands your products and processes. **Only the knowledgeable can simplify safely**

> Make sure you **excel at risk management**, not emotive risk assessment. Be data driven, proportionate and sensible. Only those with a mature and intelligent approach to risk can simplify

> **Design in simplicity from the start.** It's cheaper! Always involve the users and key stakeholders from the start

Step Two: Use Small Groups of Smart People and Move Fast

Simplicity's best friends are small groups of users. Spectators are not welcome. In simplification the *"law of small"* applies: *"The quality of work increases in direct proportion to user involvement."*

User input is critical. Leadership must provide the resources and commit to implement what the users decide will work. Avoid involving those who created the complexity in the first place.

Adopt a **smart timeline**. The easiest way to make things complicated is to give people too much time. To achieve simple solutions three ingredients are required:

> A good plan
> Good people
> Not quite enough time

Step Three: Identify the Core Purpose

Identify the core purpose of the system, procedure or process you are trying to simplify.

Step Four: Process Map Reality

Get the users to process map (visualize) what they actually do.

Step Five: Remove the Non-Essentials

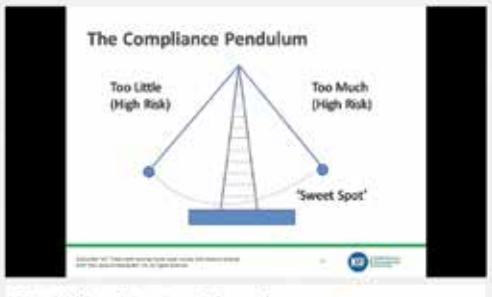
Time for some brutal thinking; remove anything that doesn't contribute to the core purpose.

Step Six: Protect What You've Simplified

Having worked so hard to simplify, protect what you've created. Removing complexity is like creating a vacuum. It's unnatural. Unless you prevent people from putting the complexity back in, they will do just that!

SIMPLIFICATION: FREE RESOURCES

At NSF we believe levels of complexity have reached crisis levels in many companies. In addition to the information contained in this Journal, please visit the NSF Pharma Biotech Consulting resources library **(www.nsf.org/info/pblibrary/)** for free simplification resources.



Webinar: The Art and Science of Simplification – How to Win Your War on Complexity

Video: How to Jumpstart Your Pharma Business by Simplifying Processes

How to Use B = M.A.t.H.

to Improve and Simplify GMP Behaviors

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

How can Simplification Alter Behavior?

Loft Insulation: To encourage people to insulate the loft space in their houses (and reduce energy bills), the UK government provided attractive, cash saving tax incentives. Unfortunately very few people took them up on their offer. After a little more research the government came back with a different incentive. Instead of a tax rebate they offered a subsidized loft clearance service. They were inundated with applications. Why?

The task of clearing decades of junk from loft spaces to permit insulation was too difficult. Offering to do this for them changed their behavior because it made it EASIER to achieve.

Motor Cycle Thefts: When Germany made the wearing of helmets a legal requirement for motorcyclists, thefts of motor bikes fell. Why?

The government had (inadvertently) made non-helmet-wearing riders easier to spot as potential motorcycle thieves. Thieves now had to walk around carrying a helmet, which increased difficulty and desire!

The Importance of B = M.A.t.H.

In a previous edition of the Journal, we provided valuable guidance on changing GMP behaviors by applying our B = M.A.t.H. model:

> To change **B**ehavior you must provide the **M**otivation, the **A**bility (make it easy), the **t**rigger event, and then make it a **H**abit

> If you're not getting the desired behavior, one or more of these elements is missing

The VITAL Importance of Ability (Ease)

Research confirms what the above examples illustrate. To change any behavior you must:

> Make the new, desirable behavior easier than the old one **OR**

> Make the old, undesirable behavior as difficult as possible

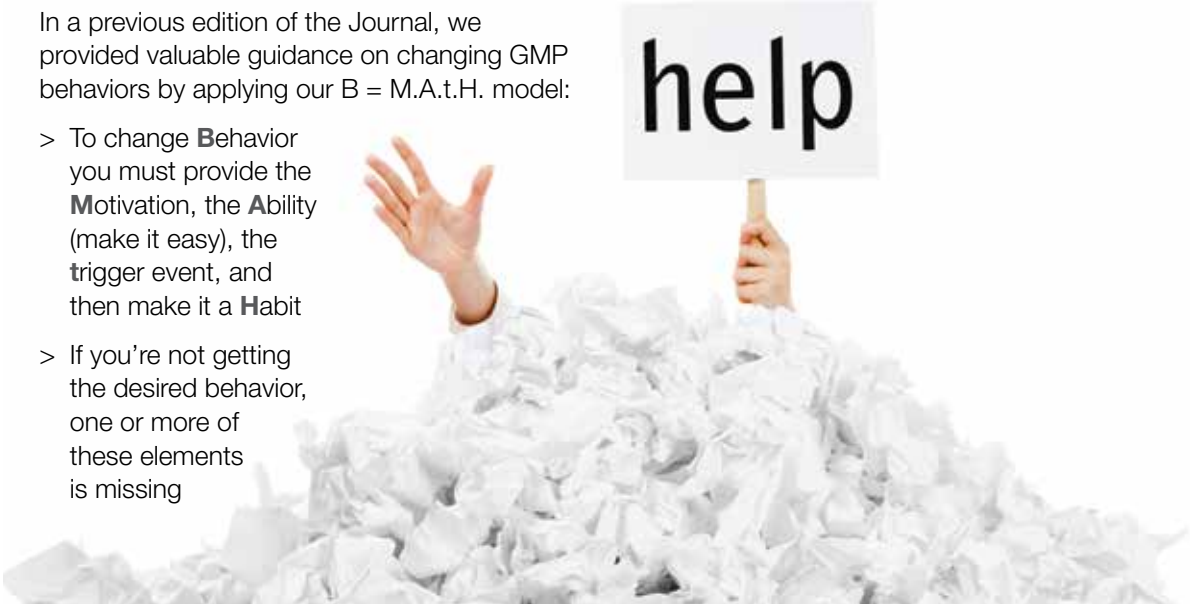
So, please remember…

> Most people will always take the path of least resistance. They will always do what is easiest

> The whole purpose of simplification is to reduce friction and make things easy to do

> All of our research suggests that you simply can't change behavior without simplifying the workplace and it's key processes first

So on the following pages are five examples of how we have successfully improved GMP compliance by focusing on simplification, human error reduction and facilitating improved workplace behaviors.



Success Story #1

SOP Simplification

What We Found

> Client had 2,456 SOPs
> 37 percent of their deviation incidents were related to SOP non-compliances. Widespread culture and acceptance of SOP non-compliance
> Average word count per SOP was 9,900
> SOPs were written for the inspector, not the user
> SOPs were usually written in isolation from the process
> SOPs were owned by QA, with no user involvement
> The average number of co-authors was five people per SOP
> How-to instructions started on page four
> SOPs were automatically given a two-year "expiry" date
> Average approval time per SOP was five days
> Five approval signatures were required per SOP
> Processes operated using "tribal knowledge" and shortcuts, not the SOPs

What We Left After NSF Simplification

> SOPs reduced by 54 percent to 1,126 by removing non-essentials
> SOP non-compliances (deviations) reduced by 85 percent
> Average word count per SOP reduced by 98 percent to 220 words per page by using pictures and schematics
> SOPs now written for the users "on the line". Content reflects their education levels and their requirements, not the inspectors
> Co-authors reduced from five to three
> How-to instructions start on page one
> SOPs tested before approval
> SOPs given six month expiry period to allow problems to be fixed and improvements made
> Approval time reduced to 30 minutes
> Five approval signatures reduced to two

Steps Taken

> Identified high-risk SOPs using deviation data
> Asked the users "Which SOPs do you hate the most?"
> Ran a two-day (distraction-free) workshop with the users of 30 SOPs identified

Tools Used

> Nine-step simplification process
> Process mapping
> Risk assessment (FMEA)
> Six Hats Thinking methodology
> Brutal thinking
> NSF behavior change model (B= M.A.t.H.)

Return On Investment

> £11.5 million in first year
> Workshop attendees then acted as simplification champions across site
> Simplification now extended to batch records

Behaviors Changed

> Simplification now seen as vital to their future
> SOPs now used, not "tribal knowledge"
> Culture of demotivated non-compliance has changed to one of motivated compliance, the place is buzzing!

Key Message

Use a distraction-free, high-intensity workshop to convince, educate, inspire and generate immediate return on investment.

Success Story #2

Simplification of Batch Manufacturing Records

What We Found

> BMR had grown to 237 pages
> Time to review and approve was 1.5 hours
> BMRs right first time were 62 percent
> Average number of errors per BMR were 28
> Number of signatures required was 110
> Due to complexity, BMRs were often completed at the end of the shift
> Order due date performance was 76 percent

What We Left After NSF simplification

> Number of pages reduced to 72
> Review and approval time reduced to 30 minutes for each BMR
> BMRs right first time increased to 96 percent
> Average number of errors per BMR reduced by 89 percent to three per batch
> Number of signatures reduced by 79 percent to 23
> BMRs completed in real time during the manufacturing process
> BMRs now owned by users/manufacturing
> 99 percent of orders released on time
> Workshop participants then took responsibility for simplifying other BMRs
> Deviation incidents reduced

Steps Taken

> Got the right people in a room with no distractions for a focused three-day workshop
> All stakeholder groups were represented
> Selected a BMR to simplify
> Agreed on core purpose of the BMR
> Each stakeholder listed their user requirements. This list was then drastically reduced using brutal thinking
> Stakeholders reviewed BMRs to identify only essential instructions, GMPs and license requirements, everything else was removed
> Smaller BMRs were then redesigned to make them easy to follow
> Approval checklists were generated
> Simplified BMR was tested (piloted) on-line

Tools Used

Same as Success Story #1 on page 8.

Return On Investment

Annual savings of £2.5 million for just one product line.

Behaviors Changed

> Manufacturing ownership of BMRs
> Improved accountability
> More attention to detail through checklists
> Dramatically improved levels of trust

Key Message

Brutal thinking is key. Remove the non-essential. BMRs have multiple stakeholders who want different things, most of which are non-essential. BMR simplification creates considerable fear, particularly in QA. The sensible use of FMEA helps to remove these fears. When simplifying BMRs, be prepared for lots of resistance and emotion.

Success Story #3

Simplification and Improvement of Deviation and CAPA System

What We Found

> 12 percent increase in deviations per year peaking at 2,890
> 45 percent of these were repeat incidents
> 67 percent of deviations attributed to human error
> Corrective actions focused on retraining and adding more detail to SOPs
> 27 percent of batches for product release delayed because of overdue investigations
> Investigations completed by QA most of the time
> 89 percent of investigations completed on day 29 to satisfy the 30-day KPI
> Incidents not risk ranked
> 46-page deviation reporting SOP
> 11 different deviation categories
> Absolute chaos

What We Left After NSF Simplification

> 87 percent reduction in repeat incidents
> 92 percent reduction in human error deviations
> In the first 12 months, less than five percent of batches were delayed being released
> Investigations now done by certified investigators from multiple functions
> 80 percent of investigations are started within 60 minutes
> Incidents are risk ranked immediately
> Deviation reporting SOP reduced to seven pages (excluding problem solving tool kit)
> Number of deviation categories reduced to the two that matter (active and latent)

Steps Taken

> We first compared their deviation system with best industry practice, gaps closed within six months, then “train the trainer” sessions on problem solving and human error prevention

> The term “root cause” was subsequently banned and replaced with “error chain”

> The 30-day KPI was removed and replaced with KPIs that encouraged the right behavior

> During the education programs the client re-designed its deviation reporting form and simplified their SOP. This included a simple problem solving tool kit

Tools Used

> Culture change education. The client had, over many years, developed a firefighting mind set and culture. To change this, education had to precede simplification

> Education focused on best industry practices, effective problem solving and human error prevention

Return On Investment

Although a final monetary figure isn’t available, it will be large. Just look at the reductions in repeat incidents and firefighting.

Behaviors Changed

Before we started, deviations were perceived as an inconvenience. When we left every incident was viewed as a learning opportunity and catalyst for continuous improvement.

Key Message

The key to this significant success was education. To simplify anything you must have a small group of educated and dedicated people to show others what to do. The rest will then follow.

Success Story #4

New Product Introduction Into a Contract Manufacturing Organization

What We Found

> Time from contract acceptance to release of first batch was six months; 50 percent more than the competition

> Schedule adherence for release of first batch was <40 percent

> High level of intervention was needed from the contract giver

> Customer feedback was “Love your staff and respect your quality system but it’s too expensive, too unpredictable and takes too long when introducing new formulations to your facility”

What We Left After NSF Simplification

> 60 percent reduction in lead time for project completion

> 30 percent reduction in GMP deviations and change control requests

> 15 percent reduction in cost of quotations associated with new product introductions

> Customer base growth of 150 percent in two years, increasing plant utilization by 20 percent

> Renewed confidence in the future working as a lean, client-focused contract manufacturing organization

Steps Taken

> Run a voice of the customer program

> Generate a swim lane diagram showing process flow, utilizing inputs from all stakeholders

> Analyze the swim lane diagram to identify gaps, overlaps, complexity and ambiguity

> Analyze the outputs to ensure the process is made parallel where possible, not linear

> Use risk management tools to identify key areas that may/have suffered from variation, error or GMP deviation

> Modify the process flow chart accordingly and road test on a real or model new product

> Update and simplify SOPs to include flow charts, indicators, clear job roles and expectations; all stakeholders review and buy in to the changes

> Implement the SOPs and an effectiveness check on the first three projects and then quarterly for the next 18 months

Tools Used

> Listen to tough feedback from people you trust, accept reality and act on it

> Process flow charting/swim lane diagrams

> Model plans, checklists and project charters

Return On Investment

> Investment was 108 staff days from start to end

> Revenue grew over £1.5m over the next 12 months, promoting confidence in the company and allowing for inward investment elsewhere on site

Behaviors Changed

> Confidence in new, self-directed project teams
> Belief in project status reviews; more trust and fewer recriminations
> Customers came back, in less of a parent-child relationship with less oversight and verification needed

Key Message

Less stuff = more love.

Success Story #5

Implementing a New Vendor Assurance System

What We Found

> Purchasing can place orders from unapproved suppliers
> QA is not aware of changes until the consignment arrives
> Audit of suppliers revealed considerable quality risks, or required additional checks and controls
> Unapproved materials are used in formulations, meaning 20 percent of products are held in quarantine pending QA
> Current process poses quality and financial risks to the company

What We Left After NSF Simplification

> Installed an end-to-end process for introducing new suppliers (pending, approved and certified), aligned to GMP and business needs
> Built relationships and awareness of role across QA, planning, operations and purchasing; recognizing shared success against mutually agreed objectives
> No products held in quarantine pending QA due to vendor-related issues

Steps Taken

> Generate a swim lane diagram showing process flow, utilizing inputs from all stakeholders
> Analyze the swim lane diagram to identify gaps, overlaps, complexity and ambiguity
> Analyze the outputs to ensure the process is made parallel where possible, not linear
> Triage risk to allow resource to focus on high-risk changes
> Modify the process flow chart accordingly and road test on a real or model new supplier
> Update and simplify SOPs to include flow charts, indicators, clear job roles and expectations; all stakeholders review and "buy in" to the changes. Take time to educate stakeholders on the "know why" not just the "know how"
> Implement the SOPs and implement an effectiveness check on the first three supplier changes and then quarterly for the next 18 months

Tools Used

> Process flow charting
> Model plans, checklists and routing/ gateway charts
> Project management taking account of all perspectives/drivers from each stakeholder in the business
> Rapid decision making to exclude high-risk, unengaged suppliers quickly before investing too much in advance

Return On Investment

> Investment was 45 staff days from start to end
> Inventory and working capital was reduced by £400k, also negating the need for additional rented warehouse space
> QA batch release lead times of batches associated with supplier changes were reduced by over ten weeks
> Utilizing clearly defined gateways to certified status, the cost of incoming QC testing of materials from the best suppliers was reduced by >80 percent and cut time waiting for QC by no less than ten days
> No high-risk, unengaged suppliers are used in the supply chain, leading to fewer quality investigations, fewer supplier audits and less reliance on oversight or a person in plant

Behaviors Changed

> Quality group seen as facilitating the business, not restricting it
> Holistic return on investment to be defined for every change; changes based on value, not cost
> More teamwork and less decision making in silos

Key Message

Buy together, save together.

What Our Remediation Projects Are Saying About the Industry

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

"A study on the pharma industry's GMP remediation projects reveals a lot about us and our inability to focus only on what is truly valuable," says John Johnson.

NSF Pharma Biotech Consulting is in a unique position in that our team is regularly and intimately involved in a range of GMP remediation projects across the world and across all dosage forms. When a system or process fails to provide sufficient levels of quality assurance or inadequately maintains compliance to cGMP, the best case scenario is that your quality system identifies the issue and escalates it to the right people, and those people study the problem and apply the right resources to fix it now and for the future. Often the solution can be derived in-house utilizing the available experts within the company. However very often companies like to contact us for a different perspective on current industry thinking or for us to review and verify that the proposed CAPA will be effective across the full range of key attributes. These attributes include cost, timeframe, GMP compliance, sustainability, simplicity and ease of presentation to clients and regulators.

In cases where a third party identifies a problem for you, what are they thinking:

> What else is going wrong around here?

> Why did they let this happen?

> Why did it take me to find the problem for them?

> How can I trust them to put it right?

> How does this affect my choices and judgment on next steps?

In effect, issues of this kind erode trust. I recently presented "A Question of Trust; Hard Won, Easily Lost" at the Annual PDA Europe meeting in Berlin. GMP remediation programs following "a nasty surprise" are always more expensive than doing it right the first time and are often characterized by recriminations, politics and rapid, sometimes unpredicted change. We also noted that, without a reassuring yet challenging third party who can provide expert oversight and guidance borne from multiple remediation projects, companies can languish for months while they regroup and begin the process of GMP remediation. Our services have proven to get people back on their feet sooner, helping to realign "muscle memory" and getting the organization moving forward with renewed purpose and confidence.

In almost every case we work on, the need for an expensive GMP remediation program is caused by five main drivers:

1. Inadequate foresight of what the future will demand of your business
2. Inadequate management of resources and knowledge
3. Staff turnover, lack of investment in education, coaching and development of leaders and subject matter experts
4. Inadequate identification, evaluation and mitigation of risk to ICH Q9:
   > Poor Performance in
      - Quality planning
      - Management review processes
      - Internal audits
      - Preparedness for regulatory inspections
5. Inadequate Quality Management System (QMS), especially:
   > Poor alignment of the QMS to the needs of the wider business
   > Poor analysis of potential root causes leading to ineffective CAPA
   > Over-complexity

Remember, simple processes always deliver predictable, measurable results.

If you recognize any of these in your organization, how are your personal or departmental objectives defined so that these are resolved before they become a crisis? What resources or budgets are assigned to these five key issues?

Let's focus on simplification, the theme of this Journal. Time and again, we note that remediation programs flounder or get mired in complexity. If your program seems to go from warp speed to snail pace and back again, if it's hard to see at a glance what is done and what is to be done and by whom, or if you can't rely on the CAPA to prevent the risk of recurrence, chances are that the program itself is over-complex. Worse still, the CAPA you are completing may be adding to complexity in the quality system. And, of course, this will store potential GMP non-conformance for the future. Complexity causes staff to struggle to follow complex SOPs, QC methods and work instructions or to complete the records as prescribed. Complexity is a hidden cost that sometimes makes us look like busy fools!

> **"If you can't explain it simply, you don't understand it well enough."**
>
> Albert Einstein

Making a process simple is vital but not easy. It is human nature to surround oneself with equipment, tools, processes, information and co-workers; many people actually derive self worth from the complexity of the task they are doing even though, especially when under time pressure, that task may be prone to error and variation.

So, in any project involving a paradigm shift, make sure you have someone alongside you who nudges you in the ribs and whispers…

> ***How can we make this less prone to error?***
> ***How can we reduce the number of steps in this process?***
> ***How can we make the key steps more apparent, their standards better defined and the checks more explicit?***
> ***How can we reduce the risk of omission, overlap and human error?***
> ***What can we eliminate from this process to make what is critical more apparent?***
> ***And especially in a GMP remediation program, how can we make sure that each of the following are considered when deriving each CAPA:***

Visit our resources library (**www.nsf.org/info/pblibrary**) and view the below video and webinars for more information on our simplification projects and personal and organizational well-being:

> ***Video:*** How to Jumpstart Your Pharma Business by Simplifying Processes
> ***Webinar:*** Firefighting to Fire Prevention – How to Reduce the Risk of GMP Deviation and Crisis in the Pharma Industry
> ***Webinar:*** The Art and Science of Simplification – How to Win Your War on Complexity

> **"Knowledge is a process of piling up facts; wisdom lies in their simplification."**
>
> Martin Henry Fischer

NSF Health Sciences Medical Devices

The Benefits of Simplification in the Medical Device Industry

by James Pink, Vice President, NSF Health Sciences Medical Devices

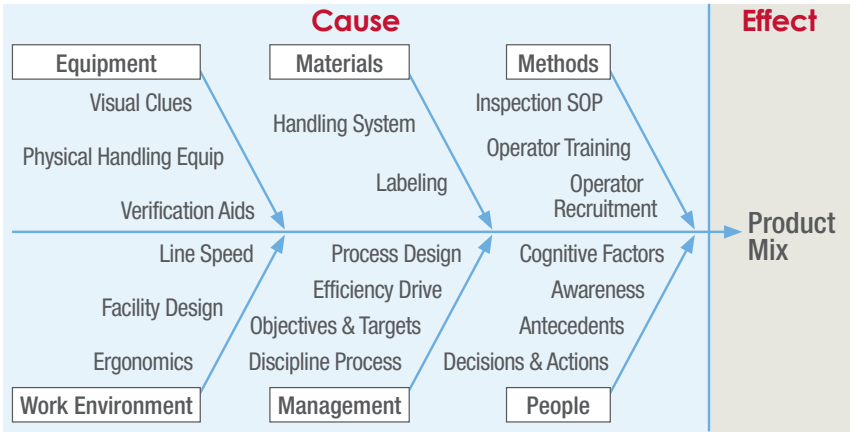
Our medical devices team explains a recent simplification project in orthopaedic implant manufacture.

Orthopaedic implants have a range of sizes that enable the surgeon to select a patient-specific solution. A typical orthopaedic manufacturer has products with similar shape(s) processed in a variety of batches, all converging toward the same cleaning, packaging and labeling line.

When a series of advisory notifications relating to product mix-ups occurred, we were asked to help establish a solution.

The Problem

We investigated the potential causes of orthopaedic components being released from manufacturing with the incorrect product or label. An Ishikawa diagram summarized the key vulnerabilities.



Stress Test of the System

To see if the manufacturer's process was vulnerable we stressed the system. For an entire shift we increased the manufacturing demand and throughput, and introduced batches of two similar size implants. We included an additional verification step away from the manufacturing line. It was concluded that with only a ten percent increase in line speed, we began to experience incorrect labeling.

Investigation Phase

To determine why this occurred, we examined the inspection and test methods as well as operator training and competency evaluation criteria. The inspection method had an array of instructions associated with different implants yet much of the text was the same. We hypothesized that due to the monotony of the instruction, a possible attention issue may have contributed to the failure. The work instruction also included too much detail found to have been included as a result of a customer audit finding.

Simplification Strategy

Next, we undertook a process risk analysis utilizing a process flow chart blended with critical-to-quality and safety attributes and knowledge of the likely health effect of each failure mode. We concluded that the highest risks to the patient in these process steps related to product mix-up as well as general contamination or damage during processing.

We modified the inspection instructions by splitting them into 20 different product codes attributed to the size and type of implant. The inspection method identified the three most critical risks and included the actual patient impact. Prior to repeating the experiment, we separated the inspection methods so that the operator had to walk away from the line to select the method.

Conclusion

After increasing the line speed and repeating the size ranges, the issue was eliminated. Lessons learned: focus on what is important, avoid over-complicating work instructions and standard operating procedures, and actually "qualify your process" using appropriate stress tests.

Tech Talk

Brexit Implications for UK Pharmaceutical Administration

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

With the historic vote by the UK to leave the European Union I have been asked by many of our clients and colleagues "What will the vote to leave the EU (Brexit) mean for pharmaceutical quality management and the role of the Qualified Person (QP)?" So this is my attempt to provide some answers.

The only thing that is certain is that we are facing at least two, and probably more, years of unprecedented uncertainty. So much of the following inevitably contains a high degree of educated guess work. This uncertainty is likely to impact investment decisions by companies, but I am not qualified to speculate on this area and will focus primarily on the possible legal and administrative impacts.

The European Medicines Agency (EMA) will move its headquarters from London to another EU Member State. Discussions are already underway regarding the relocation; the Member States most keen to host the Agency at the moment are Sweden, Denmark and Italy. Only around seven percent of the current EMA management and secretariat come from the UK at the moment, so the activities of the EMA should actually be largely unaffected.

One possibility is that the UK will seek to join Norway, Lichtenstein and Iceland in the European Economic Area (EEA). If this were to be the case, then in practical terms for medicinal products comparatively little would need to change.

If the UK does not elect to join the EEA and chooses to adopt what I will call the "Swiss model" for medicinal products, the UK will then be required to make much more profound changes. This would mean the UK would adopt EU pharmaceutical legislation into UK law so that UK medicines law shadows EU medicines legislation while it remains outside of both the EU and the EEA. This strategy would be less disruptive if a Mutual Recognition Agreement (MRA) or an Agreement on Conformity Assessment and Acceptance (ACAA) is agreed upon with the EU. Historically such agreements usually take much longer than two years to negotiate but given the unique circumstances of a Member State leaving the EU, this may be possible within the two-year exit timeframe.

Pharmaceutical Legislation

Until recently most EU pharmaceutical legislation has been issued as directives, which means that these directives have already been transposed into UK legislation; mostly in The Human Medicines Regulation 2012 (Statutory Instrument 2012-1916). However, this statutory instrument (SI) will almost certainly have to be revised as it has been issued under the authority of the European Communities Act 1972, which will have to be repealed, and

contains numerous references to EU directives. The replacement legislation could revert to the Medicines Act 1968, which was the governing legislation in the UK prior to 2012, but hopefully will be substantively unchanged.

So what will UK pharmaceutical legislation look like moving forward outside of the EU? It all depends on the outcome of the negotiations between the UK and the EU. The most logical outcome for medicinal products would be for the UK to adopt the Swiss model. This would require the minimum re-writing of the existing UK legislation and could be applied to future EU changes whether they are issued as directives or regulations.

GMP and Other Regulatory Guidance

The UK Medicines and Healthcare products Regulatory Agency (MHRA) has always had significant input into the development of GMP and other medicinal product guidance. This will undoubtedly continue via organizations such as PIC/S, where the MHRA currently has chairmanship, and probably the International Council for Harmonisation (ICH). I would expect the MHRA will become members of the recently re-organized ICH so they can continue to participate in this highly influential forum and continue to provide their valuable contributions to the evolution of GMP and other guidance.

Qualified Persons (QPs)

The role of the QP is already enshrined in UK law by SI 2012-1916 so providing that the UK agrees to mirror EU legislation, as described above, there should be no change in terms of the requirements to become a QP or in the QP's role in the certification of batches.

Obviously, if the UK is no longer in the EU, UK QPs will no longer be able to accept certification of products by EU QPs and vice versa. This is likely to increase the workload for QPs in the UK and in the EU for product coming from the UK.

If the UK can quickly agree to an MRA or an ACAA with the EU, there will be no need for re-testing when product moves between the UK and the EU. Without an MRA or ACAA, the required re-testing will create a significant barrier to trading medicinal products between the UK and the EU.

QPs who became eligible in another EU Member State and are named on UK Manufacturing Authorizations (MIAs) would be an issue. Hopefully, some sort of grandfather clause might be negotiable but it is possible that they may no longer be eligible. The reverse is also true with UK origin QPs no longer being able to be named on MIAs in the remaining 27 EU states.

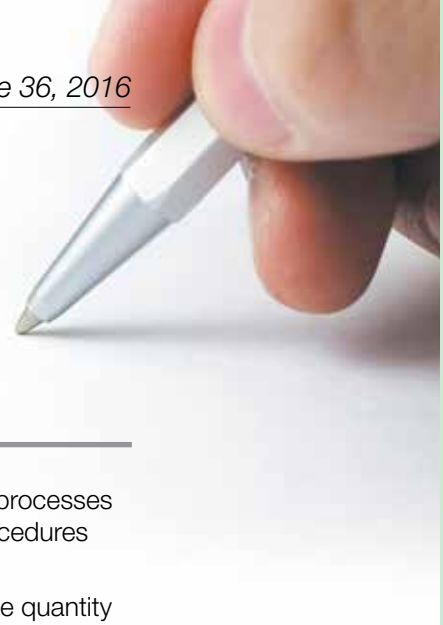
Regulatory Inspections

If an MRA or an ACAA is agreed upon prior to the UK exiting the EU, not much will change between the UK and the EU. Without the MRA or ACAA, UK companies would be subject to inspections by EU authorities and the MHRA would be required to inspect in EU member states, which they do not have sufficient inspection resource to do at present.

The UK will need to agree on their own MRAs with the countries who currently have MRAs with the EU. This should be possible but will add to the MHRA's work in the short term by conducting any assessments needed and additional inspections if there is a lag between the UK leaving the EU and the signing of UK MRAs.

The MHRA could lose its access to the EudraGMDP database and, in that case, their inspection outcomes would no longer be entered.

Another aspect of the split is the large quantity of inspection work subcontracted from the EMA to the MHRA. Presumably this will cease, which will result in a significant reduction in income for the MHRA. This is also likely to cause delays in EMA being able to perform "third-country" inspections.



Marketing Authorizations

(With thanks to Helen Erwood of ESPL Regulatory Consulting)

A lot is unknown but it is likely that the MHRA will have to mutually recognize centralized (EU) authorizations and introduce a process to issue a national MA (much like Norway and Iceland do at present).

If a centralized EU MA is held by a UK company the MA holder will need to have a legal entity within the EU/EEA.

For decentralized and mutual recognition procedures, companies will probably begin moving away from the UK quite quickly. For existing marketing authorizations linked to an EU procedure, where the UK is the Reference Member State (RMS), in the long term, the role of the RMS will need to migrate to another EU Member State. Transfer from one RMS to another currently requires the initial RMS to prepare an assessment report. The UK MHRA will be hard-pressed to do this for every mutual recognition procedure (MRP) and decentralized procedure (DCP) that it leads, so some form of interim process for this will be required.

Where the UK is a Concerned Member State (CMS) in an established EU MRP/DCP, pan-EU variations procedures will no longer apply in the UK, leading to a significantly bigger workload for the MHRA; the UK will have to assess changes for all previously EU-based MAs, with the consequential increase in approval times.

Degrees of regulatory disruption will be inevitable over the coming months, even if the MHRA introduces some pragmatic processes to migrate licenses linked to EU procedures into UK national procedures.

The EMA also subcontracts the large quantity of assessments to the MHRA, which again will presumably cease and this may in turn mean that the EMA response times increase for handling applications, etc.

Clinical Trials

This area is in the process of major change with the implementation of the Clinical Trials Regulation 536/2014. As this is a regulation, it has not until now required translation into UK law. This translation would now need to occur when the UK leaves the EU, if we choose to follow the Swiss model. This regulation is due to be implemented before October 2018, which could well coincide with the UK formally leaving the EU.

Pharmacopoeia

The European Pharmacopoeia (PhEur) is prepared, published and distributed by the European Directorate for the Quality of Medicines and Healthcare (EDQM), which is part of the Council of Europe, not the EU. So, providing the UK remains a member of the Council of Europe, which has a total of 47 member countries including Switzerland, not too much should change.

For questions, please contact Peter Gough at **petergough@nsf.org** or call **+ 44 (0) 1751 432 999**

Peter Gough Receives Honorary Doctorate Degree From Kingston University

On July 27, 2016, Peter Gough was awarded an honorary Doctor of Science degree for outstanding service to pharmaceutical quality management by Kingston University, London. Peter attended Kingston University as an undergraduate in the late 1970s and earned his MSc in analytical chemistry from Kingston in 1981.

Peter has worked in numerous pharmaceutical quality management roles in a career spanning more than 40 years. From 2003 to 2005 he was the European industry topic lead on the ICH Q9 expert working group that wrote the international guideline on pharmaceutical quality risk management. He subsequently received the Leveraging Collaboration Award by the U.S. FDA for his contribution to the online ICH Q9 briefing pack.

Regulatory Update

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

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

EU News

ATMP GMP

Article 5 of Regulation 1394/2007 on Advanced Therapy Medicinal Products (ATMPs), which amended Directive 2001/83/EC, requires the Commission to draw up guidelines on Good Manufacturing Practices (GMPs) specific to ATMPs. After the Commission issued a consultation document on GMP for ATMPs in late July 2015, many commented on the need for a separate ATMP GMP rather than simply referring to EudraLex Volume 4 Part I and producing a new Annex to define the unique requirements for ATMPs. The Commission has persisted with the concept of a separate GMP for ATMPs and on June 28, 2016 published a draft guideline for comment; comments should have been submitted by September 26, 2016.

This draft ATMP GMP guideline applies to both marketed and investigational ATMPs and is 66 pages long. It is essentially a slimmed down version of EudraLex Volume 4 Part 1 with additional expectations specific to ATMPs. A concern must be that by writing a GMP guide specifically for ATMPs, the people working with ATMPs, who are mostly academics and clinicians, are not encouraged to look at the rest of EudraLex Volume 4 and so fail to appreciate some of the fundamental elements of GMP.

The QP section acknowledges that for some ATMPs the normal expectations, such as retesting on importation from third countries or release only after full QC testing, may not be able to be applied due to the short product shelf-life or the limited amount of material available.

ICH News

ICH Expansion

At the ICH Assembly meeting in Lisbon in June 2016, another 14 observers were added:

> Association of Southeast Asian Nations (ASEAN)
> Biotechnology Innovation Organization (BIO)
> Central Drugs Standard Control Organization (CDSCO, India)
> Council for International Organizations of Medical Sciences (CIOMS)
> Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS, Mexico)
> East African Community (EAC)
> European Directorate for the Quality of Medicines & HealthCare (EDQM)
> Health Sciences Authority (HSA, Singapore)
> International Pharmaceutical Excipient Council (IPEC)
> Ministry of Food and Drug Safety (MFDS, South Korea)
> Roszdravnadzor (Russia)
> Food and Drug Administration (TFDA, Chinese Taipei)
> Therapeutic Goods Administration (TGA, Australia)
> United States Pharmacopeia (USP)

At the Lisbon meeting, two new members were also added: the International Generics and Biosimilars Association (IGBA) and the World Self-Medication Industry (WSMI).

New Topics: M9 and M10

Two new topics for international harmonization were endorsed by the Assembly in June 2016. The first is the development of a guideline on biopharmaceutical classification system-based biowaivers. The aim of the future ICH M9 Guideline is to achieve worldwide harmonization of the applicability of biowaivers and the data needed to support such applications. The public health benefits include reducing unnecessary clinical trials, and facilitating the production and availability of good quality medicines especially in low- and middle-income countries.

The second new topic is related to bioanalytical method validation, for which recent regulatory requirements have been introduced in the EU, Japan and USA. The proposed ICH M10 Guideline will address the discrepancies between these provisions and those from other ICH regulatory members. A harmonization approach will promote rational and effective studies and facilitate global drug development.

Data Integrity

Guidance on data integrity has been coming thick and fast over the past couple of months! The major developments are:

> In July the UK MHRA published a new blog on data integrity which included a draft of a revised version of its 2015 guidance. This revision is being made to extend the guidance to be applicable to all GxPs as the 2015 version was GMP focused. There is a three-month public comment period with a closing date of October 31, 2016

> Also in July the WHO published the final version of its data integrity guidance. It is very readable and is probably the best guidance to use for training purposes

> In early August PIC/S published a 41-page draft guide on data integrity. The document states that the period from August 10, 2016 to February 28, 2017 is for "Implementation of the draft on a trial basis and comment period for PIC/S Participating Authorities" so we can expect participating authority inspectors to immediately start applying the expectations in this draft

> Also in mid-August the EMA published a set of 23 questions and answers on data integrity on its website

US News

FDA Highlights

On June 24, 2016, FDA released the technical reference document, Quality Metrics Technical Conformance Guide, for the implementation of the previously released Draft FDA Guidance for Industry on Requests for Quality Metrics. This technical guidance discusses how to electronically submit the quality metric data and does not try to resolve any outstanding industry concerns about what quality metrics should be reported and by whom. The draft guide provides the format of the electronic submission, its data element specifications, mandatory data elements and optional data elements. The guide also details data validation rules.

This guidance follows on the heels of much feedback from all sectors of the U.S. drug industry (Generic, OTC, Rx, Biologics) on the FDA's July 2015 draft Guidance for Industry on Requests for Quality Metrics which had significant industry feedback suggesting changes.

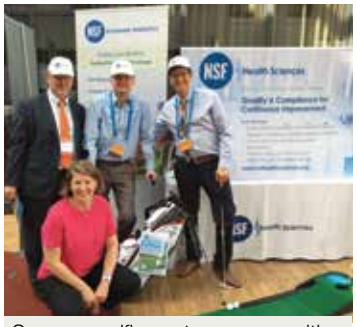
NSF News...

John Johnson in action on stage during the PDA keynote session in Berlin.

1st PDA Europe Annual Meeting

June 28-29 2016, Berlin, Germany

At PDA Europe's inaugural event to the pharmaceutical industry on June 28-29, 2016 in Berlin, John Johnson, Executive Director of NSF Health Sciences Pharma Biotech Consulting and expert in steriles, presented the keynote session "A Question of Trust – Hard Won, Easily Lost". John gave his insight into how the pharma industry is perceived by the general public and regulators; and how trust and credibility can be eroded by poor adherence to cGMPs. Overall, the event was attended by 249 visitors from 19 countries and provided a first-hand opportunity for businesses to stay current and comprehend future advances in both modern sterile manufacturing and quality oversight. Contact John at **johnjohnson@nsf.org** to receive a copy of his presentation.



Summer golfing extravaganza with the NSF Health Sciences team at booth 21. Pictured left to right: John Johnson, Heather Taylor, Martin Krainz and Benjamin Koepsell.

Congratulations to the winner of the Golf Bag: **Mr Olivier Depaire from Sanofi.**

Annual NSF Qualified Person Alumni Grows from Strength to Strength

The tenth annual Qualified Person alumni meeting in June 2016 had a tremendous turnout of 63 alumni members plus guest speakers, including senior MHRA inspectors and senior managers. Alumni membership is restricted to "core" delegates who took four or more modules from our QP program.

A huge amount of business was carried out with updates, continuing professional development and some specialist topics, and the meeting also provided fantastic networking opportunities. This year's alumni also gave us an opportunity to welcome the newly qualified QPs and to provide our best wishes to those about to take their vivas. The group also launched its new logo. To reflect the support and friendship offered by the membership, the officers of the alumni chose "a family of QPs, trained by NSF." Mike Halliday, Vice President of NSF Pharma Biotech Consulting, said "It is a pleasure to work with such highly committed and enthusiastic delegates on the courses and to have the chance to keep in touch long after they've moved on to the challenges that busy careers bring." Congratulations to the officers and Stella Pearson-Smith for coordinating a brilliant event!

Next year promises to be another great success, so email Stella at **QPpharma@nsf.org** if you plan to attend the June 2017 event to ensure a provisional place is reserved.

NSF Health Sciences Welcomes Shritin Shah and Jesse Ahrendt to the team

We would like to welcome Executive Directors Shritin Shah and Jesse Ahrendt to our U.S. NSF Health Sciences Pharma Biotech Consulting team. Shritin and Jesse are accomplished professional consultants with over 40 years collective consulting and industry expertise.

Shritin has over 25 years of experience with considerable expertise consulting in regulated industries. His core strengths include expert skills in GMPs and quality systems regulations, with emphasis on validation as it applies to the pharmaceutical industry. He has successfully hosted and managed cGMP inspections by FDA field inspectors, including being well-versed in and hands-on with addressing OAI statuses, warning letters and consent decrees. Shritin has a successful record of auditing, assessing, remediating and establishing procedures and processes to dependably address regulatory compliance with U.S. FDA, DEA and NRC.

Jesse is an experienced industry consultant with over 15 years of active engagement in pharmaceuticals, biologics, medical devices and biotechnology as a certified quality auditor and quality engineer. Jesse's areas of expertise include QA compliance management, third-party vendor evaluation, cGMP manufacturing and quality systems. This includes experience in validation, deviation/CAPA/EC, auditing, mock inspections, supplier qualification and QMS/risk assessment/SOPs. His work has included activity on most continents and working alongside many cultures creating and executing product and process validations per international compliance requirements.

NSF in the Community

When the NSF team isn't hard at work, they're involved in the community. Recently, staff members raised some funds for Macmillan Cancer Support.

NSF Father and Son Cycle from Coast-to-Coast

In the spring school half term, Mike Halliday, Vice President of NSF Pharma Biotech Consulting, and his 13-year-old son Ben cycled 150 miles to raise money for Macmillan Cancer Support. Their coast-to-coast trip across England started from Whitehaven in Cumbria and ended in Newcastle upon Tyne. Over £600 has been raised for Macmillan Cancer Support so far.

As well as raising funds to support those in need, this was a great personal challenge for both father and son and some quality time was spent together. Mike also emphasized the importance of his young man learning the importance of social responsibility and getting involved. Well done Mike and Ben from everyone at NSF!

NSF Team Completes The Herriot Way Walk

On the cold evening of June 17, 2016, a small team of the NSF office in Kirkbymoorside, England and friends from the local running club set off walking the Herriot Way to raise money for Macmillan Cancer Support. The circular walk in the beautiful Yorkshire Dales takes in high, open fells and rolling, heather-clad moorland, including one of the highest points in Yorkshire, Great Shunner Fell. The walk was approximately 52 miles (84 km) with an overall height gain of around 7,700 feet (2,350 m) and an equal amount of descent. Despite the guide book stating it is generally considered to be a four-day walk, the team completed it in just 21 hours – a great achievement but with a few sore feet by the end. Over £1,824 has been raised so far. Well done to the team who completed the walk for such a great cause.

From left to right: Peter Winter, Dean Wise, Sally Edwards, Nicola Wise, Martin Lush, Jess Lush and Gordon Harrison.

Forthcoming Courses

What's planned for October 2016 – May 2017

Statistics for Ongoing Process Verification – Analyzing and Trending Data
October 11-12, 2016

Manchester, UK

Course Fee: £1500 plus VAT

Pharmaceutical Law and Administration
October 17-21, 2016

York, UK

Course Fee: £3395 plus VAT

Free QP Seminar for Prospective QPs and Sponsors
October 18, 2016

York, UK

Course Fee: FREE

Pharmaceutical Legislation Update: Continuing Professional Development for Qualified Persons & Technical Personnel
October 18, 2016

Milan, Italy

Course Fee: €625 AFI members plus VAT
€690 Non AFI members plus VAT

Pharmaceutical GMP Audits and Self-Inspections
A17638

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

October 31 – November 4, 2016

Amsterdam, The Netherlands

Course Fee: £2810 plus VAT

Medicinal Chemistry & Therapeutics
November 14-18, 2016

York, UK

Course Fee: £3395 plus VAT

Pharmaceutical GMP
November 21-24, 2016

Amsterdam, The Netherlands

Course Fee: £2240 plus VAT

Pharmaceutical Formulation and Processing, Part 1
January 16-20, 2017

York, UK

Course Fee: £3395 plus VAT

GMP for Biological and Biotechnology Products
February 28 – March 3, 2017

Manchester, UK

Course Fee: £2300 plus VAT

Pharmaceutical Formulation and Processing, Part 2
March 6-10, 2017

York, UK

Course Fee: £3395 plus VAT

A – Z of Sterile Products Manufacture
March 13-17, 2017

Manchester, UK

Course Fee: £3000 plus VAT

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.

NSF Health Sciences Pharma Biotech Consulting

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

Pharmaceutical GMP
March 20 - 23, 2017
Amsterdam, The Netherlands
Course Fee: £2300 plus VAT

Techniques for Effective Failure Investigation
March 21 - 22, 2017
Amsterdam, The Netherlands
Course Fee: £1540 plus VAT

Pharmaceutical Legislation Update: Continuing Professional Development for Qualified Persons & Technical Personnel
March 22, 2017
Manchester, UK
Course Fee: £770 plus VAT

Pharmaceutical GMP Audits and Self-Inspections
(An IRCA Certified Pharmaceutical QMS Auditor/Lead Auditor Course)
A17638
March 27 - 31, 2017
Manchester, UK
Course Fee: £2880 plus VAT

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

Quality Management Systems
April 3 - 7, 2017
York, UK
Course Fee: £3395 plus VAT

Pharmaceutical Microbiology
May 15-19, 2017
York, UK
Course Fee: £3395 plus VAT

Free QP Seminar for Prospective QPs and Sponsors
May 16, 2017
York, UK
Course Fee: FREE

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

Error Reduction: A Case Study

Problem

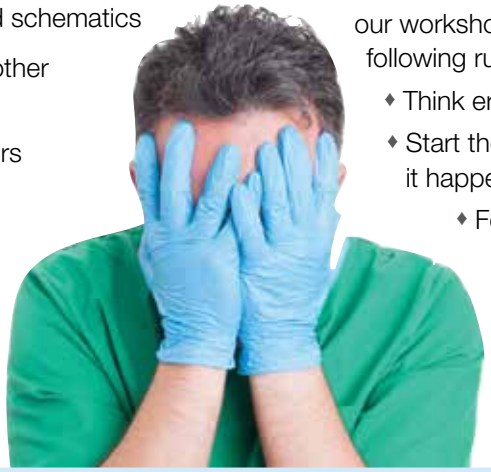
One of our clients was unhappy with their annual $1.2 million error bill and unnerved by their legacy risk. Most deviations were excused as human error, and over 68 percent of incidents reoccurred. What did they do to reduce their bill and sleep easier at night?

Solution

NSF provided customized education on error prevention, which gave the client a greater understanding of the top ten error prevention practices. During our customized workshop (www.nsfhumanerrorprevention.org) we looked at their error trends. Most were due to procedural problems, non-compliances, errors and mistakes. Through the training, the client:

> Identified the latent failures that needed fixing, using the Klein Process. These included:

- Excessive detail making SOPs over complicated and impossible to follow
- Not enough use of pictures and schematics
- Too many cross-references to other documents and SOPs
- SOPs written in a language users couldn't understand
- Lack of user ownership
- SOPs written to satisfy the auditor, not the user
- SOPs not available in the workplace



> Simplified processes. Using our simplification process, they removed unnecessary detail to create user-friendly documents

> Stopped training, started educating. Instead of the "read and understand" approach to training, we introduced them to the 10/20/70 approach to education, which consists of ten percent factual content, 20 percent practical exercises and immediate practice using case studies, and 70 percent practical application, reinforcement and coaching in the workplace. This simple model has since transformed their business

> Embedded the top ten error prevention practices. During our workshop the client developed the following rules:

- Think error chain, not root cause
- Start the investigation within 30 minutes, from where it happened, not from behind a desk. No exceptions
- Focus on fixing the latent errors. Fix the system, not the person
- Think PACA, not CAPA (prevention, not correction)
- Start measuring what matters, such as repeat incidents

Results

After 18 months, the client has achieved:

> Reduction in repeat incidents from 68 percent to less than five percent

> Savings in direct labor costs of $900k and falling

> Severe quality incidents down by 37 percent

> Less waste not yet quantified

> Faster cycle times

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