

# Journal

Issue 28, Spring 2014

## Data Integrity

*A Modern Day Challenge*



Health Sciences  
Pharma  
Biotech

Formerly NSF-DBA

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# welcome

Welcome to the spring 2014 issue of The Journal.

We are now officially NSF Health Sciences Pharma Biotech! Our new business unit now gives us a far greater bandwidth than before in the areas of consulting, auditing and training/education services.

We also continue to grow and have added a number of high caliber staff to our offices in Washington, DC, Boston, and York, UK. In this issue of The Journal we meet John Johnson and Roy Strunin, and our next issue will introduce George Toscano and Luba Skibo and the expertise they bring.

If you have not worked with us before, or feel “tired” with your existing service providers, then try us – you will not be disappointed!

We hope you enjoyed the previous issue of The Journal (available online at [http://www.nsf.org/newsroom\\_pdf/pharma\\_journal\\_issue\\_27.pdf](http://www.nsf.org/newsroom_pdf/pharma_journal_issue_27.pdf)) and as a result spent some time thinking about what you and your firm need to do differently in 2014.

2014 will without doubt be another year of significant change in the pharma biotech sector. The combination of the rapidly changing regulatory environment and the difficult business environment makes it even more important that you adopt the three principles we highlighted in our previous Journal:

**Embed and sustain a quality culture throughout the organization**

**Implement and improve a QMS that is risk-based and drives improvement and efficiency**

**Ensure your workforce is educated in the “know why” not just the “know how”**

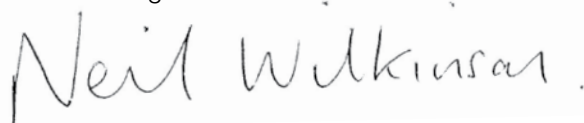
Remember, **survival is optional**.

As promised, we bring a mix of articles to this Journal, including some hot topics:

- Data integrity – an area of focus for pharma with far-reaching business consequences if you get it wrong
- Quality metrics – we set the scene for a new approach
- CAPA effectiveness – we invite you to climb the ladder with us
- Regulatory updates – from the EU and US
- Our pharmaceutical GMP auditing course and IRCA certification – going from strength to strength
- Our growing EU activities – with local language staff in key markets

As ever, I hope you enjoy this issue of The Journal.

Best regards



Neil Wilkinson



Neil Wilkinson  
President,  
NSF Health Sciences  
Pharma Biotech



# Tech Talk



## DATA INTEGRITY

MAKE SURE THIS HOT TOPIC DOESN'T BURN YOU... OR YOUR SUPPLIERS, CONTRACT MANUFACTURERS OR CONTRACT LABORATORIES

by Maxine Fritz, EVP of NSF Health Sciences Pharma Biotech, George Toscano, Senior Director of Quality Systems, Pharmaceuticals, Biotech and Biologics, and Darren Jones, Consultant, NSF Health Sciences Pharma Biotech

**How confident are you that there are no data integrity issues within your firm, or within the many suppliers, contract laboratories or contract manufacturers you use in the development, manufacture and supply of your products or services?**

There has been a noticeable increase in the past year or so in the number of significant enforcement actions taken by regulators, particularly the US FDA and the UK MHRA, related to data integrity. These have included the refusal to accept new product filings and the refusal to allow products to be marketed if manufactured at a site with known data integrity issues.

Over the years, there have been many previous data integrity-related issues that have tainted our industry. Current enforcement trends suggest that certain firms have failed to take heed of the history and importance of this topic.

The term **data integrity** is broad and may have widely different meanings depending on the specific context. In this article, the scope of "data integrity" is limited to pharmaceutical

quality control laboratories, an area where many high profile data integrity problems are found, though the concept could easily apply to any electronic storage system or part of the supply chain utilized at a pharmaceutical manufacturer. This article provides an overview of some of the different types of and concerns regarding data integrity.

Any unintended change to data as the result of a storage, retrieval or processing operation (including malicious intent, unexpected hardware failure and human error) is a failure of data integrity.

Data integrity is an issue currently receiving plenty of attention from both the US Food and Drug Administration (FDA) and the UK's Medicines and Healthcare Products Regulatory Agency (MHRA). Although data integrity issues are not new, companies are being cited more frequently during inspections for observations related to data integrity, and agencies are even relying on evidence of data integrity issues from other regulatory bodies as the basis for taking enforcement actions against a pharmaceutical manufacturer.



Section 801(a) of the US Federal Food, Drug and Cosmetic (FD&C) Act states, “If it appears from the examination of such samples **or otherwise**” that an article is misbranded/adulterated, then the “article shall be refused admission” to the US. It is this “or otherwise” phrase that enables the FDA to rely on **other** regulatory agencies’ findings. Specifically, the Regulatory Procedure Manual (RPM), Chapter 9-6 Detention Without Physical Examination (DWPE), explains that DWPEs can be enacted when “an inspection conducted by FDA or by foreign or other government authorities under a Memorandum of Understanding (MOU) or other agreement” reveals evidence of non-compliance with FDCA 801(a). FDA has a “confidentiality commitment” with MHRA which enables the agencies to share non-public information about drug products, including any data integrity concerns. This confidentiality commitment specifically mentions cooperation between FDA and MHRA to “assist the other in conducting its regulatory functions.”

As part of their standard inspection process, FDA and MHRA verify the accuracy and validity of various data, with a heightened focus on quality control activities. Relatively simple checks on systems and records frequently identify significant concerns, which are particularly pervasive with older data handling systems where more manual intervention is permitted. Cases of deliberate falsification of results and manipulation of data to make a failing result meet acceptance have been discovered – a GIANT RED FLAG to the regulators about a firm’s quality culture.

The two sections highlighted present some common data integrity concerns found throughout pharmaceutical quality control laboratories, and provide recommendations for preventing potential breaches in data integrity.

## Common Data Integrity

**Audit Trails** – For electronic data acquisition systems, audit trails are not available or are not enabled; therefore, there is no record of data modifications or deletions. Surprisingly, companies are still cited for not enabling the audit trail feature on their software systems, even though this is a simple but powerful guard against data integrity issues.

**Unique User Logins** – Each user should have a unique username and password for both the analytical software and the operating system. This is essential for tracing work performed to a unique individual, and is critical for Good

## Common Data Integrity Issues Found in Microbiological Laboratories:

Traditionally, microbiological laboratories have relied on manual testing and recording operations, which opens the door to significant issues with data integrity. The issues observed often relate to the falsification of data; for example, recording fewer contaminants from a sample to ensure that the result meets the specification is a simple data integrity problem. How can a manufacturer be sure that company or contract laboratories are not guilty of falsification of data? Reviewing data trends can provide useful indicators – unlikely scenarios such as purified water systems with no microbial excursions or clean rooms with no environmental monitoring excursions are simple triggers that should prompt further investigation. If it looks too good to

be true, it may well be! Spot checks of samples against the recorded results can also provide a good benchmarking indicator of whether there should be any concern regarding the integrity of recorded data.

Microbiological samples are often read and then rapidly discarded, so it is sometimes difficult to obtain evidence of falsification. Physical spot checks of samples in the incubator can be a powerful technique; if, for instance, physical spot checks identify the “first four purified water excursions ever” to be found on a site, it is likely these are not the first excursions.

Microbiological data patterns can also identify data integrity and falsification with a simple review of the data. For example, media growth promotion results can yield interesting patterns; there have been instances where only even

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## Issues Found in Chemistry Laboratories:

Manufacturing Practice (GMP) compliance and data integrity. Companies are often cited for having multiple users share the same username and password or, worse yet, having all users logging in as the administrator with privileges that may include the ability to modify or delete data.

### User Privilege Levels –

Each data acquisition system should have defined user levels based on the role the user will have in the system. Examples of common user levels include analyst, supervisor, manager and administrator. Privileges assigned to each level should be clearly defined and commensurate with the requirements for each user type. Examples of privileges include the ability to create

methods, modify integration parameters, reprocess data and modify data.

### Unofficial “Test” Injections

– Some firms have been cited for injecting samples prior to beginning an official sequence. This practice results in essentially generating data for products, but not reporting the data.

### Control Over Processing

Methods – Use of high performance liquid chromatography (HPLC) processing methods (including integration parameters) that are not defined or controlled. This includes the practice of manual integrations without justification or approval, and processing injections in the same sequence with different processing methods and integration parameters.

Another example of this practice includes processing standards that are used for quantitation of samples with different processing methods (integration parameters) without justification provided.

### Control Over Electronic

Systems – Failure to establish adequate controls over computer systems to prevent unauthorized access or changes to electronic data. This can include failure to have mechanisms to prevent unauthorized user access to the system, and ability to rename, move, delete or not save file results. Mechanisms should be in place to ensure that files cannot be accessed outside the analytical software (e.g. via the operating system) and edited, moved, renamed or deleted.

numbers of colonies were recovered (apparently to make the averaging of the duplicate samples easier). When looking at growth promotion testing, it is often worth checking that the specification limit calculations have been performed and applied correctly. These are often found to be incorrect, resulting in missed out of specification (OOS) results. If something looks odd in the data, investigate it in detail, obtain supporting evidence, monitor results in the incubator over the course of the test and look at historic trends to assess data integrity.

A final recommendation for any quality control laboratory, whether chemistry or microbiology, is to be vigilant with laboratory paperwork. A recent case contained different versions of OOS investigations; the formal investigation that went for approval contained only one failed result, whereas a second unofficial and unapproved

version recorded more excursions that appeared to have been hidden and not reported.

Overall, the crucial component to any data integrity review is to ensure that data is recorded exactly as intended and, upon later retrieval, ensure that the data is the same as it was when it was originally recorded. In short, data integrity aims to prevent unintentional changes to information, eliminating the potential for significant data integrity errors occurring in the pharmaceutical manufacturing process.

Evaluating a firm for data integrity issues requires a specific skill set and consulting/auditing toolbox, often not held within many pharma firms.

Our authors have significant experience of working with data integrity, both as regulatory inspectors (Maxine with FDA, Darren with MHRA) and all as consultants.

Discuss this article or your data integrity needs further

# Your CAPA Effectiveness

## How Far Up Are You?

by Martin Lush, VP, NSF Health Sciences Pharma Biotech

### Words of Wisdom

“Success does not consist in never making mistakes but in never making the same one a second time.”

Your investigations and CAPA system is vital, having a business critical impact. It protects your patients, drives continuous improvement and helps manage your risks and company reputation. What could be more important?

However, despite being a high profile issue for many years, not all firms have got the message yet. Where does your firm stand?

Regulators continue to find that firms do not have effective CAPA systems, as evident from repeat incidents, often occurring time and again, despite an investigation report closed in the mythical “30 days”. With regulators criticizing firms for repeat incidents, it’s clear that some CAPA systems are not fit-for-purpose. Their CAPA “effectiveness ladders” are broken.

**Your Task:** Start at the bottom of the ladder. The first step. If you  check all the criteria, move onto the next step. How far up the CAPA Effectiveness Ladder do you get? If you don’t get to the top, you are putting your business at risk.

### Why is Your Investigation and CAPA System So VITAL?

- Allows you to assess the risk associated with every deviation incident
- Helps you to learn from your mistakes...so they never happen again
- Acts as a catalyst for driving continuous improvement
- Tells the regulators a lot about your attitude to quality and risk, your leaders and your culture
  - ◆ Lots of repeat incidents = “They don’t care.”
  - ◆ Low numbers of deviations (incidents hidden?) = “Can they be trusted?”
  - ◆ Human error common root cause = “They don’t understand.”
- Protects your company legacy and reputation.

- Reports allow the incident to be clearly understood years later by someone with no prior knowledge. Reports tell the whole story

- **Never** written just for the inspector or auditor

- Investigators trained in quality risk management and problem solving tools and techniques

- Simple methods used (such as Ishikawa, 5 Whys, brain storming, Six Thinking Hats)

- Have high levels of emotional intelligence and questioning skills

- Focus on data-driven decisions, not emotion or bias

- Always look for multiple causes, never a single root cause

- Always ensure the investigation is not done in isolation and consider the bigger picture

- Open, transparent and blame-free culture

- Incidents seen as fuel for continuous improvement

- Metrics focus on driving down repeat incidents, not total number

- Investigations seen as organizational priority, not inconvenience

- Culture of quality, not compliance

- Obsession with prevention and improvement, not firefighting

- Investigations done by process experts, not only QA

- Attitude that deviations are an opportunity to improve, not bad

- Mistakes seen as learning opportunities!

- No such thing as human error as the main bucket of root cause

- No “close in 30 days” focus for all investigations

# Success Ladder



**9**  
Intelligent Trending and Knowledge Management

- Critical, major and minor findings all trended
- Incidents grouped and investigated as one
- Fast escalation processes
- Sharing of knowledge company wide
- Focus = Predicting future failures and continuous improvement

**8**  
Effectiveness Check and Follow Up

- CAPAs reviewed and checked for effectiveness before final closure
- Learning shared across enterprise

- Quality of CAPAs from an investigation is more important than quantity
- Corrective actions have clear, realistic measures of success and timing
- Focus on moving toward a preventive action system that predicts issues and prevents their occurrence in the first place
- Ensure CAPAs are shared / extended to other sites / systems / products where a similar issue could occur
- It's about prevention, not reaction

**7**  
Incident Report That "Tells It All"

- Incidents investigated proportionate to risk – firstly to patient
- Objective criteria used to risk rank incidents
- Failure mode effect analysis a key tool

**6**  
Focus on Strong CAPAs

- Deviation reporting form 2-3 pages max
- Reporting system accessible to all
- Incident report raised *immediately*
- Investigation started *immediately*
- Investigations at the scene, never from behind a desk

**5**  
Trained (Certified) Deviation Investigators

**4**  
Incidents Are "Risk Ranked"

**3**  
A Simple Incident Reporting System

**Fact:** You can't fix problems unless you understand your processes.

- You must have an institutional understanding of:
  - ◆ Product "key quality attributes"
  - ◆ Process critical control points
  - ◆ Basic GMPs
  - ◆ What can happen when things go wrong
- People understand the "whys" and what questions to ask

**2**  
Process Knowledge and Expertise

**1**  
Culture and Leadership Behavior

## How Far Up The Ladder Are You?

- If you got to the top, well done. Your company is well led and has a bright future
- If you're at or near the top, work hard to stay there. Complacency can kill
- Stuck in the middle? Look at what you have to do and act quickly. Being in the middle isn't good enough
- Stuck on the first step? Help your leaders to understand what is expected of them before it's too late. If only on Step One = firefighting and crisis management
- **If you don't act, the regulators will act for you (and with justification)**





## Pharmaceutical GMP Auditor Course and Auditor Certification Scheme Goes from Strength to Strength

By Mike Halliday, NSF Health Sciences Executive Director and Pharmaceutical Auditor Program Lead

### Success grows!

**Since the scheme was launched in 2012, about 400 auditors have taken our certified auditor course. These include PICS inspectors from three different agencies, and certification is also now an internal requirement for auditors from three major multinational pharmaceutical companies.**

When we first designed the scheme and took it to IRCA ([www.irca.org](http://www.irca.org)) for initial discussions, we knew it was a key topic for the industry and something which was much needed by the industry, auditors and patients. We are, however, delighted with the level of success of the course and the scheme.

It continues to gain great reviews for customer satisfaction from those who have attended and their managers who see the impact the training makes on their company. Already we have over a dozen courses planned around the globe for 2014, including both public courses and in-house courses for companies. By the end of the year, we will also be delivering courses in a number of key European languages.

In a recent press release (<http://www.irca.org/en-gb/about/news/IRCA-announces-new-Pharmaceutical-GMP-Auditing-Scheme/>) IRCA announced the revision of the scheme which was originally launched as a pharmaceutical quality management system scheme. However, with changes to legislation and guidance it has become possible to name

it more accurately as the pharmaceutical GMP auditor scheme. This is great news personally for me and my colleagues, as when we first designed the scheme our original objective was to have a GMP auditor development and certification scheme to fully prepare and recognize auditors working in the GMP field. IRCA has also now gained MHRA support for the program and we regularly have inspectors from influential pharmaceutical regulatory agencies attend the course.

At NSF Health Sciences, we believe we now have a product that will really enhance pharmaceutical GMP auditor skills and improve the consistency and value of pharmaceutical audits. Many of us wish such a course/scheme had been available to us earlier in our careers!

With the increased focus in the pharmaceutical industry on modern Quality Management Systems and the critical role of internal auditing and supplier auditing as a key part of the QMS, the competence of auditors will become a more major area of focus, as well as a key business need.

So, if you as an individual auditor, or your firm, has a need to develop its pharmaceutical GMP audit competency via our pharmaceutical GMP auditor certification program, or seek auditor continuing professional development opportunities, please contact Gill Gibbeson, our course administrator, at [ASlpharma@nsf.org](mailto:ASlpharma@nsf.org) or me at [mikehalliday@nsf.org](mailto:mikehalliday@nsf.org).

For more information please email **Mike Halliday** at [mikehalliday@nsf.org](mailto:mikehalliday@nsf.org) or visit [www.nsf.org](http://www.nsf.org)



# Career Path Icons

*One of the most frequent questions tutors are asked after one of our training courses is "That was great, but what should I do next?"*

**It is clear that many of you are wisely considering where you want to be in five years.**

As such, we are introducing some tools to help you see how a training or development course can fit in with your continuing professional development (CPD) requirements or career path. Our new career path icons will help you select courses which would logically fit together or which former delegates have linked and found useful. We will also have posters of "what next options" at most of our major events, along with tutors to answer questions. Give it a go, see what your career path could look like and talk to the course tutors on your next event.

Some of these paths are fairly clear, for example:

- A delegate from the Good Manufacturing Practice (GMP) course meets the prior knowledge requirements for the auditor course and may want to move into auditing
- Some delegates from the GMP course are hungry for more knowledge and the Pharmaceutical Quality and GMP Master of Science (MSc) program is of interest\*
- An auditor will require CPD in some technical areas (such as QMS, analytical testing or dosage form specific training) and will probably choose technical modules from the Pharmaceutical Quality and GMP MSc program\*
- An analyst is likely to want more detail in method validation, the latest updates on OOS, etc
- A senior manager may want to attend elements of the QP course to understand the role and duties of the QP or pharmaceutical law

Trainers are always happy to talk to individuals about their personal requirements and make suggestions about best ways forward. For the QPs, this ongoing support comes through our free gap analysis and tutor support meetings.

\* (selected modules from our QP program)

## Our Career Path Icons

 Active Pharmaceutical Ingredients/Excipients	 Quality Leadership Program (US)
 Audit/Self-Inspection	 Qualified Person Training (EU)
 Biopharmaceuticals/Biotechnology	 Quality Management Systems
 Clinical Trials/Investigational Medicinal Products	 Risk Management
 Good Manufacturing Practice	 Senior Management
 Laboratory Management/Quality Control	 Statistics
 Pharmaceutical Law/Regulatory Affairs	 Sterile Products
 Pharmaceutical Manufacturing	 Supply Chain and Distribution

For more information about career paths with NSF Pharma Biotech, contact [mikehalliday@nsf.org](mailto:mikehalliday@nsf.org)



#### Words of Wisdom

*Measured in time of transport and communication, the whole round globe is now smaller than a small European country was a hundred years ago.*

**John Boyd Orr**  
– Nobel Prize winner and first Director-General of the United Nations Food and Agriculture Organization (FAO)



**Health Sciences**

# Building Bridges Across Europe



As NSF Pharma Biotech evolves, we are seeing not only an expansion of pharma related services but also a geographic extension beyond traditional markets.

Stephen Engels, Principal Associate for NSF Pharma Biotech Europe, is located in Switzerland and is heading this initiative. He is exploring new opportunities in the key strategic markets of Italy, France and German-speaking countries, building local expertise in the local language to meet the needs of global business today. Share this expansion news with your colleagues in these markets.

Some early initiatives include collaboration with the Italian Pharmaceutical Association, AFI, to offer a range of pharmaceutical educational workshops at its annual congress in Rimini in June 2014, sponsorships and speaker engagements at PDA events across Germany, and the development of industry relevant webinars and seminars.



## Upcoming Webinar:

### Human Error

Tuesday, March 4, 2014

15:00 – 16:00 (Central European Time)

– **free of charge.**

Register online now to avoid disappointment or contact Stephen directly at **[EUpharma@nsf.org](mailto:EUpharma@nsf.org)**



To receive the latest initiatives from **NSF Pharma Biotech** across Europe, sign up to our quarterly Journal at: **<http://nsf-dba.com/journals>**

### Targeting QPs in the Netherlands

**No charge seminar** with guest speakers from **NSF Pharma Biotech** and **Derks & Derks B.V. Consultancy** on **March 27, 2014** from **12.30 to 17.00 CET** at the **Carlton President hotel, Utrecht**. For more info contact **[QPpharma@nsf.org](mailto:QPpharma@nsf.org)**

# Expert Corner

## “Laser focused delivery allied to team engagement”



...Says NSF's new Executive Director John Johnson "can easily get undermined if the personal touch is not used throughout a project, particularly at the diagnostic stage."

Using some simple diagnostic tools, an engaging style and the experience that comes with 30 years of experience in the pharma/biotech sector, John believes that whether the task is associated with perpetual inspection readiness, organizational change, facility upgrades or management approach, the leader has to bring people along and understand the key question, "what is in it for me?".

Keeping the momentum of a transformation requires constant communication, encouragement, focus and creativity. It requires

the team to see incremental improvements along the way and to be able to contribute in a way that creates a path for learning whilst building team and individual confidence.

Taking into account his experience at a variety of multinationals including most recently as VP, International Quality Operations at Hospira, John is passionate about the role of

*Keeping the momentum of a transformation requires constant communication, encouragement, focus and creativity*

management at all levels in an organization, "Of course, setting up a right-sized, agile and insightful quality management system is key, but we should never underestimate the role our people have in providing energy, oversight and development to the QMS".

Starting in the next issue, NSF Pharma Biotech is setting up an Expert Corner. John will be on hand to answer your queries on anything from pharmaceuticals to fly fishing, so email your questions, remarks or words of wisdom to **AskJohn@nsf.org**

Email your questions, remarks or words of wisdom for our first Expert Corner to **AskJohn@nsf.org**

### Words of Wisdom

*The team architecture means setting up an organization that helps people produce that great work in teams."*

Jay Chiat – Chiat/Day Advertising

# Regulatory Update

## Words of Wisdom

Quality is everyone's responsibility.

W. Edwards Deming

## EU Pharma News

### EudraGMDP Database

In April 2013, the EMA announced that it had upgraded its EudraGMP database to include information on Good Distribution Practice (GDP) in addition to Good Manufacturing Practice (GMP). The new database is called EudraGMDP.

EudraGMDP will be gradually updated by medicines regulatory authorities in European Union (EU) member states with distribution-related information and will be maintained on an ongoing basis. The additional information will include:

- Wholesale distribution authorizations
- GDP certificates
- Statements of non-compliance with GDP
- Registrations of manufacturers, importers (including information on their suppliers) and distributors of active substances

The new system follows the introduction of a new module on planning GMP inspections in countries outside of the EU in December 2012. This module, which is not publicly accessible, was developed to make better use of inspection resources by sharing of information among EU regulators and avoiding redundant inspections.

In December 2013, the EMA announced that the new version of the EudraGMDP database will include statements of non-compliance that will contain information on the nature of the non-compliance and the actions taken or proposed by the issuing authority.

When the non-compliance data was first

published in December 2013, 83 non-compliance reports were revealed. The top six countries account for 69 of these non-compliances, as follows:

- |              |              |
|--------------|--------------|
| 1. India: 35 | 4. UK: 3     |
| 2. China: 22 | 5. France: 3 |
| 3. US: 4     | 6. Brazil: 2 |

This information is publicly available at <http://eudragmdp.ema.europa.eu/inspections/logonGeneralPublic.do> and firms should use it within their QMS processes.

### Falsified Medicines Directive (FMD) Implementation

By end 2013, four EU member states (Finland, Italy, Poland and Slovenia) had still not implemented the FMD in their national legislation. In December 2013, the European Commission issued a warning to these countries asking them to respond to the Commission within two months. The Commission is likely to take these member states to the European Court if they do not implement the directive early in 2014.

So far, the impact of implementing the FMD has not been as problematic as some had feared with regard to very few, if any, reported shortages of medicinal products due to issues with importing active pharmaceutical ingredients (APIs) from outside of the EU. However, this could be partly due to the fact that many companies imported and stockpiled APIs ahead of the July 2, 2013 deadline for implementing the new import requirements. So, some problems may still emerge once these stockpiles are exhausted.





### Qualified Person API Declaration Template

A final version of this template that was circulated in draft form back in December 2010 had still not been published by the end of 2013. Information from regulatory agencies indicates that a final version of the template was adopted by the Quality Working Party and the Inspectors Work Group in September 2013. Since then it has had to wait for adoption by other bodies; e.g. the Coordination Group for Mutual Recognition and Decentralised Procedures (CMDh) and it is hoped that it will be published in the first half of 2014.

### GDP Guidelines

On November 5, 2013, a revision to the GDP Guidelines, which completely replaces the version that was issued in March 2013, was published. The newer version, which became effective on November 24, 2013, corrects factual mistakes identified in sections 5.5 and 6.3 of the March 2013 guidelines.

The new text in 5.5 says that "Medicinal products that are nearing their expiry date/ shelf life should be withdrawn immediately from saleable stock either physically or through other equivalent electronic segregation." In the old text, medicinal products that are already beyond their expiration date were also included.

The changes in 6.3 were necessary because they might have led to misunderstandings. The revised text requires that "Medicinal products returned from a customer (...) should only be returned to saleable stock if they are returned within an acceptable time limit, for example 10 days." The old text required that they "should

always be returned to saleable stock if they are returned within an acceptable time limit...".

### FMD Safety Features

It has been recently reported that the European Commission has completed its impact assessment and is proceeding to draft a delegated Regulation to propose the following:

1. That the composition, format and carrier of the unique identifier will be fully harmonised across the EU. The unique identifier will be placed in a 2D barcode and contain the manufacturer code, a serialization number, a national reimbursement number (if present), the batch number and the expiry date.
2. Medicine authenticity will be guaranteed by an end-to-end verification system supplemented by risk-based verifications by wholesale distributors. Medicines will be systematically verified before being dispensed to patients. Medicines at higher risk of falsification (returns or medicines not being distributed directly by manufacturers) will be additionally checked at wholesaler level.
3. The repository containing the unique identifiers will be set up and managed by stakeholders; i.e. the 'European Stakeholder Model (ESM)'. National competent authorities will be able to access and supervise the database.

This delegated Regulation will first be published as a draft and the final version is not expected to be adopted by Commission until the end of

#### Words of Wisdom

*Quality is never an accident; it is always the result of high intention, sincere effort, intelligent direction and skillful execution; it represents the wise choice of many alternatives.*

William A. Foster

## Words of Wisdom

*Nothing has such power to broaden the mind as the ability to investigate systematically and truly all that comes under thy observation in life.*

Marcus Aurelius

2014, at the earliest. Publication in the Official Journal will then follow in 2015 after successful scrutiny by EP, Council and WTO.

**NOTE:** The 'European Stakeholder Model (ESM)' is the product of collaboration between the pharmaceutical industry (EFPIA), wholesalers (GIRP) and pharmacists (PGEU). This is based on a 2D bar code with a unique serial number and is designed around a central hub that will be linked to national or regional databases that pharmacists and others can use to check the authenticity of packs. The system was successfully trialled in Stockholm, Sweden, in 2009/10. The ESM system will be managed by a not-for-profit stakeholder organization.

## Draft of EU GMP Annex 15 on Validation published

The key points are as follows:

- URS has finally been added to the section on Qualification for facilities and equipment, as has Factory acceptance testing (FAT) /Site acceptance testing (SAT)

- Process Validation is divided into "Traditional" and "Continuous process verification" with a hybrid of the two allowed, as per the 2012 draft CHMP NfG on Process Validation
- Even for traditional validation there is no mention of 3 batches, which has been replaced by the requirement that "The number of batches manufactured and the number of samples taken should be based on quality risk management principles ..."
- To avoid confusion between continuous process verification and continued process verification the latter has been replaced by the term "ongoing process verification"
- There is a new section on Verification of Transportation
- Cleaning validation is required to be based on a toxicological evaluation to determine the product specific permitted daily exposure (PDE) value, as per the drafts of Chapters 3 & 5 and the CHMP Guideline on setting health based exposure limits.

## Joint Initiatives

### Generic Drug Application Inspections Initiative

In December 2013, the FDA and EMA announced the launch of a joint initiative to share information on inspections of bioequivalence studies submitted in support of generic drug approvals. This collaborative effort provides a mechanism to conduct joint facility inspections for generic drug applications submitted to both agencies. Taking part in this initiative are the FDA, EMA and the EU member states France, Germany, Italy, the Netherlands and the United Kingdom.

Key objectives of the initiative are to:

- Streamline information sharing on inspections of bioequivalence studies conducted and planned for generic drug applications (inspectional information will be shared for clinical facilities, analytical facilities or both)
- Share information about negative inspection outcomes that reveal system problems at a facility
- Conduct joint inspections at facilities all over the world
- Provide training opportunities to improve bioequivalence inspections



## US News

### Drug Quality and Security Act

On November 28, 2013, US President Obama signed the Drug Quality and Security Act into US law.

This act addresses one of the omissions from the Food and Drug Administration Safety and Innovation Act (FDASIA) – the tracking of drug products in the USA. This new law immediately pre-empts all state laws concerning drug product track and trace, including California's e-pedigree requirement that was scheduled to be effective in 2015.

This act sets numerous deadlines for pharmaceutical manufacturers:

- By January 1, 2015, manufacturers must establish:
  - ◆ A lot-level transaction history that documents each step a product takes from manufacturer to final sale for all finished-dosage forms of prescription drugs (i.e. a supply chain map)
  - ◆ A system to quarantine, investigate and validate via the history record a product suspected of being counterfeit, adulterated or stolen
- Four years after enactment, manufacturers must:
  - ◆ Affix product identifiers to each package and case of a product that include a numerical identifier, lot number and expiration date

- ◆ Verify the product identifier on each package of any returned product they redistribute
- Ten years after enactment, manufacturers must develop an electronic traceability system that identifies products down to the sales-unit level.

The act also requires the US Department of Health and Human Services (HHS) to conduct public and industry consultations on a number of topics, including standards for the interoperable and secure electronic exchange of data along the drug product supply chain. The HHS must then produce standards within 18 months of the consultations on the electronic system. HHS must hold at least one pilot project that evaluates unit-level traceability and the use of the product identifier.

#### New FDA CDER Office of Pharmaceutical Quality (OPQ)

Janet Woodcock, long-term Director of the FDA's Center for Drug Evaluation and Research (CDER), will also take on the role of Head of the FDA's new Office of Pharmaceutical Quality (OPQ) while the new office is in its initial launch phases. Janet has been a strong leader and advocate for improving pharmaceutical quality and associated FDA regulatory processes.



#### Words of Wisdom

*Fast is fine, but accuracy is everything.*

Wyatt Earp

### Words of Wisdom

Almost all quality improvement comes via simplification of design, manufacturing ... layout, processes, and procedures.”

Tom Peters – author “In Search of Excellence”

## New NSF Pharma Biotech Executive Director Joins Team with 30 Years' Global Experience



John Johnson recently joined NSF Health Sciences Pharma Biotech as Executive Director. John brings 30 years' experience in pharma biotech to NSF, having previously worked at Wellcome, Rhone-

Poulenc Rorer, Ipsen, Piramal Healthcare and most recently Hospira as VP, International Quality Operations.

John works with clients across a wide variety of educational, remedial and technical projects, bringing insight and experience gleaned from working with some of the industry's most influential business and quality leaders. He is passionate about the role of management at all levels in an organization.

Using simple diagnostic tools and an engaging style, John makes sure people feel connected, excited and responsible for any key change in their organization. “Never underestimate the role our people have...” he says. Read more from John in our Expert Corner on page 11.

## Living the NSF Mission



**Front row left to right:** NSF Pharma Biotech fund raisers: Sally Simpson, Bob Smailes (Yorkshire Air Ambulance Service), Sarah Richardson  
**Back row left to right:** Annette White, Stella Pearson-Smith, Bev Willett, Gill Gibbeson, Sally Edwards



Every year, the NSF Health Sciences Pharma Biotech UK team selects a locally-nominated charity to raise

valuable funds for. In 2013, the charity of choice was the Yorkshire Air Ambulance Service, an independent charity providing a life saving rapid response emergency service to 5 million people across Yorkshire. Thanks to a combination of fundraising initiatives, from running the Kirkby 10K to dress-down Fridays, book selling and even an inventive DVD hire system not to mention the classic raffle of food hampers, the committed fundraising team raised nearly £750 which has gone to a very worthy cause. Should you be interested in more info about the work of the Yorkshire Air Ambulance or to make a donation directly, visit [www.yorkshireairambulance.org.uk/](http://www.yorkshireairambulance.org.uk/)

## NSF can now offer auditing and certification of excipient ingredient auditing, helping to meet pending regulations

ANN ARBOR, Mich. USA – NSF International, a global public health organization, has acquired the auditing subsidiary of the International Pharmaceutical Excipients Council of the Americas (IPEC-Americas):

IPEA. These audits are important as U.S. and European regulations, and pending regulations in Brazil and China, require excipients to be

For more information visit: <http://www.nsf.org/news>





## Introducing Daily Regulatory Inbox Updates



NSF Pharma Biotech is pleased to introduce you to NSF Health Sciences Daily Dose, an insightful daily bulletin of news and views from the regulatory world. To be added to the daily distribution list, please

email [dailydose@nsf.org](mailto:dailydose@nsf.org) with your complete contact information, including your email address. Start getting daily regulatory updates to your inbox from today!

Alternatively download the NSF Health Sciences Daily Dose onto your iPhone via the App Store.



As NSF Health Sciences grows at a rapid pace, so too does the personnel in the marketing department to better support the growing needs of the business. Starting January 2014 is newcomer, Roy Strunin (pictured left) with expertise in medical devices and responsible for both Medical Devices and Pharma Biotech marketing North America.



Roy Strunin (Marketing Manager, Health Sciences N. America), Heather Taylor (Senior Marketing Manager – Global Health Sciences) and Katie Boone (Marketing Specialist Dietary Supplements N. America)

## ...nts in addition to food additive and dietary supplement ...ns and GMPs in U.S., EU, Brazil and China

safe, functional and to comply with Good Manufacturing Practices (GMP) requirements. As a result of the acquisition, NSF-IPEA

can now provide excipients auditing and certification as part of NSF's Health Sciences Pharma Biotech offering.

...oom/nsf-international-acquires-auditing-arm-of-ipeca-america

# Quality Metrics

by Neil Wilkinson, President, NSF Health Sciences Pharma Biotech

There has been a raised level of interest in the US recently on the subject of quality metrics as applicable to the pharmaceutical industry. Why? Because the FDA has expressed interest in how metrics could be used by both the industry and regulators to improve quality and better facilitate risk-based regulatory processes.

Those of us with long memories will recall that ICH Q10 Pharmaceutical Quality System also advocates for the use of “performance indicators,” aka quality metrics, to measure the health of our quality systems and our products.

If we go back to 2002, the FDA’s vision for 21st century manufacturing was:

***“A maximally efficient, agile, flexible pharmaceutical manufacturing sector that reliably produces high quality drugs without extensive regulatory oversight.”***

The 2005 concept paper that preceded ICH Q10 took this into account:

***“It is anticipated that the guideline will augment existing GMPs with modern quality system elements for pharmaceutical manufacturing, providing the opportunity for robust processes, resulting in drug substances and drug products that consistently meet their intended attributes.”***

***“The tools necessary for an effective quality system include not only the gathering of the correct data but the analysis of the data and its use in defining and prioritizing continual improvement activities.”***

ICH Q10, finalized in 2008, and now a cGMP expectation, refers to the use of performance indicators:

***“Performance Indicators that measure progress against quality objectives should be established, monitored, communicated regularly and acted upon as described in Section 4.1 (Management Review of the Pharmaceutical Quality System).”***

***“Management should have a formal process for reviewing the pharmaceutical quality system on a periodic basis. This review should include:***

- ***Measurement of achievement of PQS objectives***
- ***Assessment of performance indicators that can be used to monitor the effectiveness of processes within the PQS, such as:***
  - ◆ ***Complaint, deviation, CAPA and change management processes***
  - ◆ ***Feedback on outsourced activities***
  - ◆ ***Self-assessment processes including risk assessments, trending and audits***
  - ◆ ***External assessments such as regulatory inspections and findings from customer audits”***



# — What's Next?

So, in 2013/2014, why the focus on quality metrics from FDA?

Has our industry performance for pharmaceutical quality improved as intended by the adoption of the FDA 21st century philosophy, ICH Q10 and other guidelines that are now a cGMP expectation?

According to FDA, the answer is ... **NO**.

The numbers of field alerts, recalls, post-approval supplements and drug shortages have actually risen, indicating that industry quality overall is still not in the state of control that it should be. Janet Woodcock, Director of the FDA's Center for Drug Evaluation and Research (CDER), and a genuine leader in trying to facilitate change and improvement in the pharmaceutical sector, has publicly stated that industry has failed to adopt a continuous improvement model, despite encouragement from FDA. This includes all types of drug manufacturers – innovators, generics, OTC drugs and of course compounding pharmacies. Janet will initially head the new Office of Pharmaceutical Quality in FDA, so watch this space.

FDA issued a Federal Register notice in February 2013 to seek input on how the use of quality metrics might play a role in generating improvements in the quality of drugs and create more flexible and risk-based regulatory processes. Of over 150 comments received, only one was opposed.

So, the dialog has now begun in earnest in industry. In December 2013, the International Society for Pharmaceutical Engineering (ISPE) issued a white paper on the subject and a PDA-FDA workshop was held on the topic.

This is a significant move by FDA and could have far-reaching implications. The sad thing is that improvement in quality across the pharmaceutical sector continues to remain an elusive goal, and it again needs action by the regulators to try to improve the status quo.

Some key challenges remain:

- Agreeing to objective quality measures with consistent nomenclature and definitions for products, quality management systems, sites and firms
- Balancing retrospective measures (lagging) with forward-looking measures (leading)
- Ensuring the collection and use of measures that drive an open quality culture and the right behaviors throughout the organization
- Ensuring that data collection is simple, quick, relevant and converted easily into knowledge, trends and CAPAs
- Defining how FDA then recognizes and differentiates the ethical, good performers from those who just do the minimum or less

We will continue our discussion on this topic in the next addition of The Journal. As ever, your thoughts and comments are appreciated. Please contact us at [pharmamail@nsf.org](mailto:pharmamail@nsf.org).

## Words of Wisdom

*“Synergies are not only about cost reduction. Synergies can be access to markets, exchange of products, avoiding overlaps, exchange of best practices.”*

**Carlos Ghosn –  
Chairman and  
CEO of Renault  
and Nissan**

# Forthcoming Courses

What's planned for April – June 2014



## How to Audit – Sterile Products Manufacture

How to Audit

🇬🇧 Renaissance Manchester City Centre Hotel, Manchester, UK

**April 4**

The manufacture of sterile products is perhaps the most hazardous of all pharmaceutical production activities – failures can and sometimes do result in patient harm and death. That is why auditing of sterile filling operations is essential and why it is important that the auditor has the right knowledge and experience to conduct the audit with skill and professionalism.

This short, focused course is designed to help auditors with little or no direct experience of auditing sterile filling operations to know where the risks lie, what questions to ask and how to assess whether or not processes are under control.

**Course Fee: £735 plus VAT**

## Pharmaceutical GMP

🇬🇧 Renaissance Manchester City Centre Hotel, Manchester, UK

**April 7-10**

It is a legal requirement that all staff receive regular training in Good Manufacturing Practice. This course is designed to provide you with up-to-date knowledge of new and impending GMP regulations and current hot topics.

- Why we have GMP
- EudraLex Volume 4
- A clear comparison of EU and FDA GMP requirements
- Up-to-the-minute information on new GMP initiatives and regulations
- Practical advice on dealing with the 'difficult areas' of GMP
- An understanding of how GMP is influenced by the 5 Ps
- A panel discussion session to explore YOUR specific GMP problems

**Course Fee: £2,550 plus VAT**

## Elemental Impurities: Are You Ready?

WEBINAR

10am EDT

**April 24**

ICH Q3D Impurities: Guidelines for Elemental Impurities reached Step 2B on July 26, 2013 and was published in the Federal Register on October 23, 2013. The focus of this guideline is to provide global guidance to limit metal impurities in drug products and their ingredients. This webinar will review this guideline and what you need to know, including how to use the guideline and strategies companies should pursue to limit elemental impurities in drug products.

**Course Fee: \$100**

## Analytical Methods: Documentation, Validation and Transfer

🇬🇧 Manchester Marriott Victoria & Albert Hotel, Manchester, UK

**April 28-29**

Ensuring the integrity of the data produced by QC laboratories is essential and a key component in providing data integrity is the validation of the test methods. After attending this course you will be able to:

- Understand the purpose of analytical method validation
- Define the parameters used for method validation, i.e. validation characteristics
- Generate a validation protocol including relevant acceptance criteria
- Interpret the results of validation using appropriate statistics
- Understand best practice for analytical method transfer

**Course Fee: £1,470 plus VAT**

*Early Bird or Multiple Delegate discounts apply to some of our courses. Please visit our website, [www.nsf.org](http://www.nsf.org), for full details*




**For more information [www.nsf.org/info/pharma-training](http://www.nsf.org/info/pharma-training)**

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[www.nsf.org](http://www.nsf.org)



## Deviation and CAPA Systems – Best Practices

 Renaissance Manchester City Centre Hotel, Manchester, UK


**April 28-29**

How good is your Deviation and CAPA system... or are you at RISK? In this course you will learn..

- How to use your deviations to drive down costs and reduce complexity by removing non-value-adding activities and driving forward continuous quality improvement
- How to make repeat incidents a thing of the past
- How to apply structured, risk-based decision making tools and techniques to ensure that every incident is investigated to root cause in a consistent and thorough manner
- How to report, investigate and resolve incidents within hours, not days or weeks
- How to “triage” or prioritize deviations so that you focus your time and resources on what really matters
- How to make sure that your deviation reports provide an accurate history of events

**Course Fee: £1,470 plus VAT**

## Pharmaceutical Microbiology

 Amsterdam Marriott Hotel, Amsterdam, The Netherlands

**April 28-May 2**


In this course, for non-biologists and non-microbiologists, you will learn:

- The basic characteristics of all microorganisms found in your pharmaceutical environment, how they get there and how you can remove them
- How you can sample, isolate, count and identify these microorganisms
- How to prevent contamination of your products and processes using practical risk management and risk assessment tools and techniques
- How to interpret microbiological data in order to make the right risk-based decisions – decisions that will satisfy the regulators, protect your patients and improve your operational efficiency

**Course Fee: £3,200 plus VAT**



## Human Error Prevention and Reduction

 Marriott at Research Triangle Park, Durham, NC, USA

**April 29-30**

We have been teaching human error prevention for over five years, touching delegates from over 200 companies including regulatory agency representatives in Europe and the USA. Building on this track record, we have developed a comprehensive human error reduction program which will achieve dramatic reductions in human error and especially deviation recurrence. Our program includes training, site assessments and in-house certification.

The training in human error reduction is a core component of our program and includes three primary elements: the science of human error, investigative techniques for error avoidance and proactive approaches for error avoidance. This two-day course will help you and your staff see human error from an entirely different point of view, and provide you tools and techniques that will make a difference back at your site.

**Course Fee: \$1,775**

## How to Audit – QC Chemical Laboratories

**How to Audit**

 Manchester Marriott Victoria & Albert Hotel, Manchester, UK

**April 30-May 1**

This course is designed to provide existing auditors the necessary technical detail to enable them to effectively audit a QC chemical laboratory. It will also be ideal for personnel working within a QC chemical laboratory who wish to learn how to conduct comprehensive self-inspections. We will cover:

- Why it is important to audit QC laboratories
- How to plan QC laboratory audits
- The critical areas to focus on during the audit of a QC laboratory
- How to classify QC laboratory audit observations
- How to develop an audit aide-mémoire for auditing QC laboratories

**Course Fee: £1,470 plus VAT**



**Book your place at [www.nsf.org/info/pharma-training](http://www.nsf.org/info/pharma-training)**

# Forthcoming Courses

What's planned for April – June 2014



## Human Error Prevention

🇬🇧 Renaissance Manchester City Centre Hotel, Manchester, UK

**April 30-May 2**

If you think human error is the real cause of your quality problems then think again! It isn't. Human error is only the symptom, never the cause. It is the starting point of your investigation, never the conclusion.

Over the last five years delegates from over 245 companies and from at least four regulatory agencies have attended this course. All have gone away with very practical tools and techniques to help reduce so-called human error. Remember, error reduction will potentially save you £millions and protect you from severe regulatory action. You will go away with the tools needed to reduce errors, protect your business and drive continuous improvement.

**Course Fee: £1,910 plus VAT**

## Investigating Out-of-Specification Results

🇬🇧 Manchester Marriott Victoria & Albert Hotel, Manchester, UK

**May 2**

This course is designed to provide you with practical advice on how to investigate out-of-specification (OOS) and out-of-trend (OOT) results and make appropriate decisions that will meet regulatory expectations and add real value to your business. We will cover:

- OOS and OOT results
- Assessing the quality of laboratory data; identifying OOT and atypical results
- Practical guidance on conducting laboratory investigations
- The making of batch release decisions following OOS and OOT investigations

**Course Fee: £735 plus VAT**



## Qualified Persons Training – Practical Module

🇬🇧 University of Strathclyde, Glasgow, UK

**May 12-16**

One of the greatest challenges facing the prospective QP is gaining a practical understanding of the equipment and procedures used to manufacture and test the broad range of dosage forms produced by the pharmaceutical industry. This module will provide hands-on experience for a broad range of products and expert tuition from pharmaceutical specialists using the modern facilities of the University of Strathclyde's School of Pharmacy.

**Course Fee: £3,380 plus VAT**

## Effective Pharmaceutical Audits and Self-Inspections

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

🇬🇧 Manchester Marriott Victoria & Albert Hotel, Manchester, UK

**May 19-23**

Pressure on the pharmaceutical industry to audit has never been higher and continues to increase. Supply chain decisions and batch release decisions are being made based on audits and self-inspections. As a result, a high level of scrutiny is being placed on the training and development of auditors and self-inspectors. This course will provide delegates with the skills and techniques needed to become a successful pharmaceutical lead auditor.

This course meets the training requirements for the new IRCA ([www.irca.org](http://www.irca.org)) Certification of Pharmaceutical Quality Management Systems Auditor/Lead Auditor (PQMS).

**Course Fee: £2,750 plus VAT**

## QP Alumni

🇬🇧 York Marriott Hotel, York, UK

**June 5-6**

The NSF QP Alumni is a not-for-profit body run by past delegates for the benefit of QPs, to provide Continuing Professional Development and a forum for discussion and exchange of ideas. It is only open to those delegates who have completed four or more of our QP modules.

**Course Fee: £475 plus VAT**



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For more information [www.nsf.org/info/pharma-training](http://www.nsf.org/info/pharma-training)

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[www.nsf.org](http://www.nsf.org)



## Modern Approaches to Process Validation

🇬🇧 Renaissance Manchester City Centre Hotel, Manchester, UK

June 9-12

This course will show how the modern approach to process validation can add real value to your business and provide better protection to patients. It will start by looking fundamentally at the whole validation concept, why validation makes sense and what the objectives are. The course will explain how process validation must link to patients' needs and the regulatory requirements. It will explain how tools, such as risk management, statistics and change management, are used to accomplish this. This course will also show how these concepts can be applied to existing processes with beneficial results.

**Course Fee: £2,550 plus VAT**

## Pharmaceutical Analysis and Testing

🇺🇸 Boston Marriott Cambridge, Cambridge, MA, USA

June 10-12

A fundamental part of the product release decision is the review and interpretation of analytical data. This course will provide foundational knowledge needed to evaluate analytical data, understand the principles of method validation and expertly handle atypical or out-of-specification results and prevent data integrity issues. The course will cover commonly used analytical methods for large and small molecule testing and thoroughly review the best practices for laboratory operations supporting development and or commercial operations.

**Course Fee: \$2,950**



## Investigational Medicinal Products

🇬🇧 York Marriott Hotel, York UK

June 16-19

This course is designed to provide existing, trainee and transitional Qualified Persons with the foundation knowledge and understanding to assess and certify investigational medicinal products and to appreciate the fundamental differences between IMPs and licensed products. It will also be of value for other technical staff working with clinical trial supplies.

**Course Fee: £2,560 plus VAT**



## EU Excipient Risk Management Guide



10am EDT

June 19

A fundamental part of the product release decision is the review and interpretation of analytical data. This course will provide foundational knowledge needed to evaluate analytical data, understand the principles of method validation, and expertly handle atypical or out-of-specification results and prevent data integrity issues. The course will cover commonly used analytical methods for large and small molecule testing and thoroughly review the best practices for laboratory operations supporting development and or commercial operations.

**Course Fee: \$100**

## Risk-Based Decision Making in Sterile Products Manufacture

🇬🇧 Manchester Marriott Victoria & Albert Hotel, Manchester, UK

June 23-26

The biggest challenge facing anyone in sterile products manufacture is to deal with grey area problems which arise almost daily and which require decisions which are:

- Scientifically justified
- Based on an objective and realistic assessment of RISK
- In compliance with regulatory requirements and expectations
- And GOOD for your business!

The objective of this course is to help you improve your decision making and problem solving skills. What you learn could save your company £millions in rejected product!

**Course Fee: £2,550 plus VAT**



*Early Bird or Multiple Delegate discounts apply to some of our courses. Please visit our website, [www.nsf.org](http://www.nsf.org), for full details*



**Book your place at [www.nsf.org/info/pharma-training](http://www.nsf.org/info/pharma-training)**

NSF-DBA, NSF-Pharmalytica and Becker & Associates changed their names to **NSF Health Sciences** on January 1, 2014.



NSF Health Sciences offers the same integrity, service and innovation, now enhanced by NSF International's comprehensive range of global services and resources

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