www.nsf-dba.com

Key Topics in Sterile Products Manufacture

Short, focused courses on topics of special interest to manufacturers of sterile products

Manchester Marriott Victoria & Albert Hotel
Manchester, UK

A Practical Interpretation of Annex 1

Monday 21 November 2011

Environmental Monitoring for Sterile Products Manufacture

Tuesday 22 to Wednesday 23 November 2011

Process Simulations

Thursday 24 November 2011

NSF DBA℠
25 YEARS OF EXCELLENCE

Key Topics in Sterile Products Manufacture

The manufacture of sterile products relies for its success on the knowledge, understanding and training of all the people involved

Over the years, NSF-DBA has built a strong reputation for providing high quality training in the general areas of sterile products manufacture through our residential course entitled 'Sterile Products Manufacture'.

But we do not just train on the general aspects of manufacture. In recent years, we have introduced new courses on targeted aspects of sterile products manufacture. These include the highly popular 'Good Autoclave Practice' course and, more recently, our course 'Risk-Based Decision Making in Sterile Products Manufacture'.

Included in our portfolio of training courses for sterile products are three short, focused courses…

- A Practical Interpretation of Annex 1
- Environmental Monitoring for Sterile Products Manufacture
- Process Simulations

These courses are designed to provide you with our 'trademark' practical advice on what to do to achieve cost-effective quality assurance whilst satisfying current regulatory expectations.

Whether you are new to the industry or you have been working with sterile products for many years, these courses are for you!

For those of you who are new, we will provide you with the knowledge and practical interpretation you need to perform your duties.

For those of you with extensive experience, we will explore the detailed aspects of the topics which cause you concern and we are available at all times to answer your specific questions.

Your Tutors

Your tutors for these courses have been specially chosen for their experience of the manufacture and control of sterile products of all types, including sterile APIs and biotech products, and their knowledge of current international regulatory expectations.

Peter Monger

NSF-DBA, UK

Before joining NSF-DBA, Peter was a medicines inspector for the UK regulatory authority. He was one of two specialist inspectors for sterile products and contributed to the EU guidance for sterile products.

Mike Russell

NSF-DBA, UK

A pharmaceutical microbiologist, Mike gained his PhD on the microbiology of sterile products manufacture and has published papers on environmental monitoring. Mike has extensive experience of steriles manufacture.

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A Practical Interpretation of Annex 1

About This Course

The manufacture of sterile products is complex and carries many risks in terms of patient safety. Therefore **all** the people who are involved in the manufacture and control of sterile products **must** be trained to understand the GMP requirements and how their actions can influence product quality and patient safety.

To assist in this process, the EU has published specific GMP guidance to manufacturers of sterile products and it is essential that all people involved in steriles manufacture **fully** understand the guidance given in Annex 1.

Unfortunately, this task is made difficult by the number and frequency of amendments to the Annex. Additionally, Annex 1 contains no explanation as to **why** the regulators believe the specifics of the guidance are important to observe and what the potential consequences of non-compliance might be.

Not surprisingly, many companies have difficulty in truly understanding what is required to comply with Annex 1. As a result, the systems operated throughout the industry are diverse and variable in their effectiveness.

This one day course is designed to help you to understand the latest version of Annex 1 and to assist you in implementing compliant, cost-effective GMP practices.

What You Will Learn

The latest requirements of Annex 1 and what they really mean.

How to comply in a cost-effective manner with the specific guidance on:

- Room classifications and monitoring
- Oversealing of vials
- Personnel dress and gowning
- Disinfection and sanitisation
- Process definition and validation
- Expectations for media fills
- Sterilisation procedures and review of sterilisation records
- Filtration of gases and liquids
- Sampling and quality control
- Differences between EU and US guidance and how to satisfy both

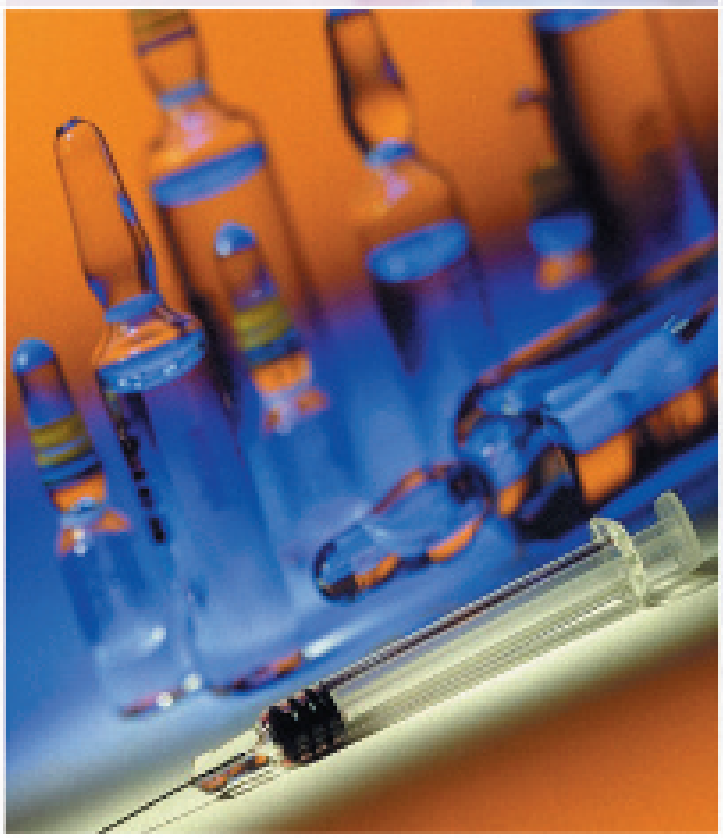
Who Should Attend

This course is designed for Production Operators, Engineers, Quality Control personnel who must enter clean rooms, Quality Assurance staff who must ensure compliance, and anyone wishing to learn more about current EU GMP expectations for sterile products.

Course Outline

We will take you through the detail of the latest version of Annex 1 and any proposed amendments. We will cover:

- Controlled environments and the activities to be performed in them
- Classification and monitoring requirements
- Isolator technology
- Blow-fill-seal technology
- Requirements for terminally sterilised products
- Aseptic processing
- Personnel
- Premises
- Equipment
- Sanitisation
- Processing
- Sterilisation
- Finishing of sterile products
- Quality control



For each section we will tell you…

- What the latest version of the Annex (and any proposed amendments) says
- What it means!
- How the guidance compares with other GMP guidelines (e.g. FDA expectations)
- How to comply effectively with the requirements
- There will be plenty of opportunity to ask questions of the tutors and get your specific concerns addressed

The course will begin at 09.00 and finish at 16.00

Environmental Monitoring for Sterile Products Manufacture

About This Course

Environmental monitoring of controlled environments represents a critically important means by which we can…

- Assess the effectiveness of our contamination control measures
- Identify specific threats to the sterility of products being manufactured

A carefully designed and well executed environmental monitoring programme can give us great confidence in the integrity and security of our manufacturing operation. However, a poorly designed and badly managed programme will be wasteful in terms of resources and misleading in terms of assuring the effectiveness of our operations and confidence in the quality of our products.

This course is designed to provide you with the knowledge and practical advice to enable you to ensure that your environmental monitoring programmes are really providing you with the information you need to demonstrate control, to assess the quality of your products and to satisfy regulatory expectations and requirements.

DAY ONE will cover the essential methodologies of environmental monitoring and will describe the means of monitoring, methods of counting particles and microorganisms in the environment and the specifics of media selection, incubation conditions and identification of isolates.

DAY TWO will be devoted to using the methodologies available to us to design an effective and meaningful environmental monitoring programme and, just as importantly, how we can use the data from monitoring to assess risk to product quality; in other words, to turn data into information that we can act on.

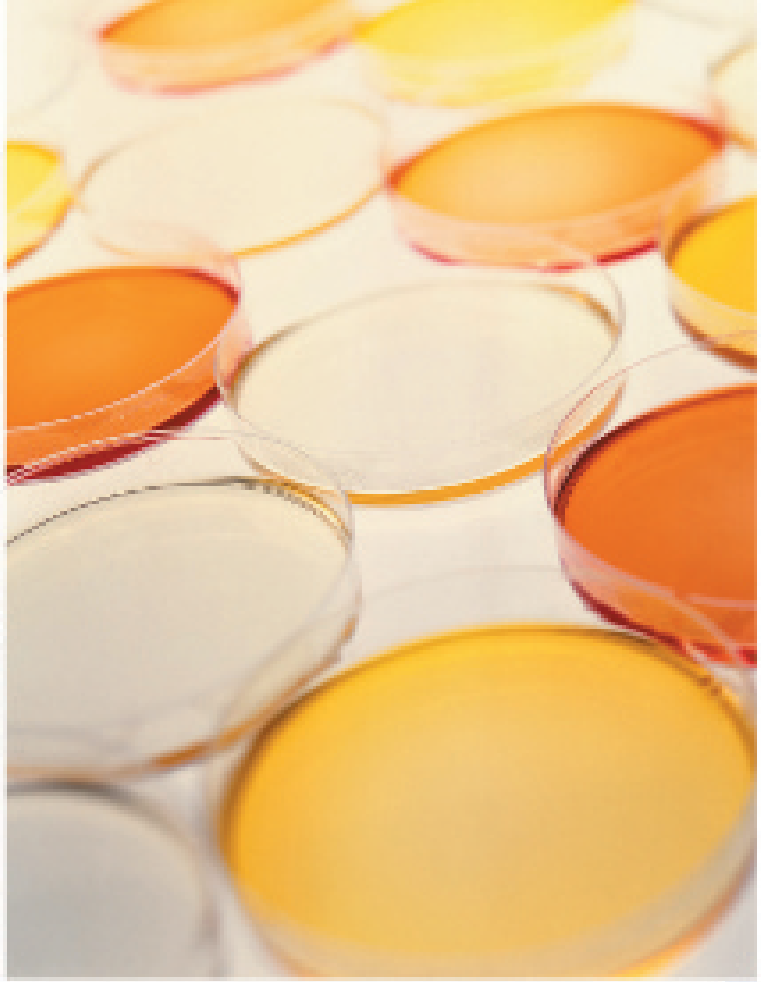
What You Will Learn

- The objectives of environmental monitoring
- The theory of particle counting
- A comparison of available microbiological monitoring techniques
- Media selection and incubation requirements
- Identification expectations
- A risk-based approach to the design of monitoring programmes
- Different approaches to data analysis
- How to set alert and action limits
- How to respond to high counts

Who Should Attend

This course will be of value to anyone involved in environmental monitoring, including:

- QC microbiologists
- Production staff
- QA personnel
- QPs



Course Outline

DAY ONE

Environmental Monitoring Methodologies

- International regulatory expectations for environmental monitoring
- Particle counting – the theory and alternative methodologies
- Microbiological monitoring techniques
    - Active air sampling
    - The case for settle plates
    - Surface sampling
    - Operator sampling
- Microbiological media selection
    - Broad spectrum vs selective media
- Quality control of culture media
- Incubation requirements
- Identification of isolates – how far should we go?

DAY TWO

Designing an Effective Monitoring Programme and Using the Data

- Objectives of environmental monitoring
- The need for two monitoring schemes
- The roles of production and quality in environmental monitoring
- A risk-based approach to the selection of monitoring sites
- Exit monitoring – benefit or burden?
- Setting alert and action levels
- Analysing the data – different approaches
- Responding to high counts – a risk-based approach

The course will begin at 09.00 on Tuesday and finish at 15.00 on Wednesday

Process Simulations

About This Course

Aseptic processing represents the most hazardous means of manufacturing medicines – just one error can lead to severe patient harm!

It is essential, therefore, that we have maximum confidence in our ability to carry out aseptic operations without introducing microbial contamination. Since we cannot reliably confirm the quality of an aseptic product by testing, we must use other data to support our belief that products are fit for sale or supply.

Process simulations using sterile medium (broth fills) represent a crucially important part of our quality assurance system for the manufacture of sterile products by aseptic processing.

However, if the results of process simulations are to mean anything, we must take care to **design** simulations properly, **conduct** them well and, most importantly, **interpret** the results to draw the right conclusions.

Done well, process simulations add significantly to our confidence in the integrity and security of our manufacturing processes. Done badly, they represent nothing more than an exercise in creative pessimism!

This course is designed to provide you with the knowledge you require to design effective process simulations which will add to your assurance of product safety **and** satisfy the requirements of regulators in Europe and USA **without** wasting your company's valuable resources.

What You Will Learn

- How to design effective process simulations
- How to set acceptance criteria for process simulations
- How to deal with problems, failures and discrepancies
- How to avoid creative pessimism!

Who Should Attend

This course is ideal for anyone involved in the design, execution and interpretation of process simulations, including:

- QC microbiologists
- Production staff
- QA personnel
- Validation scientists
- QPs

Course Outline

- **Why we carry out process simulations using sterile medium**
- **Designing an effective process simulation**
  - Choice of medium
  - Number of containers to be filled
  - Duration of simulations
  - Ensuring we simulate the whole process
  - Inclusion of interventions
  - Defining staff numbers
  - Environmental monitoring requirements
- **Specific issues**
  - What to do with 'reject' containers – to incubate or not?
  - Must **all** staff participate in a process simulation **before** they participate in routine production?
  - Must we carry out a process simulation on **every** container size or can we choose worst cases?
- **Incubation and inspection of units**
  - Expectations for incubation conditions – what temperatures, what times, which temperature first?
  - Requirements for inspection – when, how, by whom?
- **Setting acceptance criteria**
  - FDA and EU requirements
- **Dealing with failures and discrepancies**
- **Trending of results**
- **Special cases**
  - Lyophilised products
  - Sterile powders
  - Gels and semi-solids
  - Bulk aseptic operations

The course will begin at 09.00 and finish at 16.00

What Previous Attendees Said About These Courses

"Excellent first experience with NSF-DBA. Will forward details to other staff. Highly recommended."
Robert Pickering, Moorfields Pharmaceuticals, UK

"Provided a great oversight of both EU and FDA requirements and clarified the key differences."
Paul Matthias, BMS, UK

"Very good comparison of Annex 1 and FDA. Excellent overview of Annex 1 updates and guidance on what is being said beneath what is written."
Sally Barnett, Ipsen Biopharm, UK

"A comprehensive and informative course."
Matthew Davies, Genzyme, UK

"This was my first training with NSF-DBA and I hope the first of a long series as the tutors are amongst the most outstanding I have seen."
Charles-Henri Solioz, Baxter Bioscience, Switzerland

Attend More Than One Course And Benefit From Significant Cost Savings!

If you attend more than one of these courses you will benefit from a significant cost reduction.

For example, by attending all four days, the cost per day is reduced by as much as 18% **and** you benefit by gaining more valuable information.

Booking Form

Key Topics in Sterile Products Manufacture

Includes: tuition, comprehensive course notes, attendance certificate, lunches and refreshments

Excludes: all hotel accommodation and dinners (see Hotel Accommodation section)

UK: *Under UK law all UK-based applications are subject to VAT at the prevailing rate however most UK VAT registered companies/organisations can reclaim this tax.*
EU: *With effect from 1 January 2011 applications from delegates whose companies are based in EU countries will not be subject to VAT* ***PROVIDED THAT*** *valid VAT ID details are provided at the time of booking, otherwise VAT will be charged.*

VAT ID No.

OTHER: *With effect from 1 January 2011 applications from delegates whose companies are based outside of the UK/EU will be outside the scope of VAT.*

Please write clearly in **BLOCK CAPITALS**

Mr/Mrs/Miss/Ms/Dr | First Name

Surname | Job Title

Company

Full Site Address

Post Code

Delegate Tel No | Delegate Fax No

Delegate Email

Please indicate any special dietary needs:

Sterling cheques, payable on a UK bank to NSF-DBA Ltd, for the full invoiced amount (net of ALL bank charges) should be attached to this Booking Form and sent to NSF-DBA Ltd at the address below. A VAT invoice (if applicable) will be provided **(VAT Reg No. GB 927 3679 85)**. *Payments can also be made by bank transfer online (our company bank details are included on our invoice). Settlement must be received at least 10 working days prior to the course start date. Cancellations within 25 working days of the course start date are subject to charges (see Course Cancellations section). If a Purchase Order number is necessary to effect settlement of our invoice please provide it in the box below.*

Purchase Order number | Date

Authorised Signature | Cheque enclosed

To aid prompt confirmation of your booking, please ensure you submit a completed application form which bears an authorised signature and Purchase Order number.

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An NSF International Company

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

I wish to reserve a place on…

A Practical Interpretation of Annex 1
Monday 21 November 2011

Environmental Monitoring for Sterile Products Manufacture
Tuesday 22 to
Wednesday 23 November 2011

Process Simulations
Thursday 24 November 2011

I understand that the course fee is...

First/only delegate attending:

Any one day	£695.00
Any two days	£1320.00
Any three days	£1740.00
All four days	£2275.00

Additional delegate(s) from same site, for the same course:

Any one day	£556.00
Any two days	£1056.00
Any three days	£1392.00
All four days	£1820.00

All prices plus VAT at the prevailing rate where applicable – please see note on VAT charges.

The Venue

The Manchester Marriott Victoria & Albert Hotel stands on the banks of the River Irwell, near the city centre but convenient for Manchester Airport (19km), the city's Piccadilly rail station (3km), and the UK's motorway networks. Recently lovingly restored, this Grade II listed building bears many modern features. The hotel has its own car park and the Living Well Health Club with pool, gymnasium, sauna and steam room is just a few minutes from the hotel. Also nearby are the Imperial War Museum North West, Lowry Museum and Manchester's three theatres. A few minutes' walk takes you to the city's main shopping and eating district.

Hotel Accommodation

- We have a block booking of bedrooms at the Manchester Marriott Victoria & Albert, at the specially negotiated bed and breakfast rate of £107.23 (plus VAT at the prevailing rate) per delegate per night.
- As part of our improvements to the booking process, we have arranged for an online booking service with the hotel and details of how to make your accommodation booking will be included in your course joining instructions (issued to you at the time of booking). Alternatively you will be able to make a telephone booking directly with the hotel. If you need any help or guidance with the accommodation booking process, please contact our course administration team.
- Your account with the hotel should be settled at check out.
- Any charges made by the hotel as a result of you not taking up your reservation for any reason will remain your responsibility, therefore please ensure you are aware of the hotel's cancellation policy.
- Whilst places on the course will be available, we would also ask you to ensure that your booking for accommodation is made at least six weeks before the course start date as the hotel cannot guarantee bedroom or rate availability after this time.

To Book on this Course

- Fax the completed and signed form from this brochure to our Course Administrator. Your place will then be confirmed by post and a course fee invoice will be issued.
- Provisional bookings can be made via our website, in the Training Courses section. Online reservations must be confirmed by the completion of a Booking Form (pdf brochure and Booking Form files can be downloaded via the website).
- Make sure you write a Purchase Order number on the Booking Form if this is necessary for settlement of our invoice.
- Reserve a place by telephone or email (contact details are on the Booking Form), confirming as above.

Course Cancellations

Written cancellations with a full refund will be accepted up to 25 working days before the start date of the course. A cancellation fee of 50% will be payable for cancellations received between 10 and 25 working days before the start of the course. If you cancel within 10 working days of the course start date, full course fees will be chargeable. Delegate substitutions may be made at any time up to the start of the course.