NSF-DBA Medical Device Diploma

Learning through doing with experts at your side
The Medical Device Diploma – *Learning through doing with experts at your side*

NSF-DBA launch a ground breaking work based Diploma for the medical device industry.

After 18 months of development and a major survey of medical device quality and regulatory learning needs we have formulated a *body of knowledge* that has identified all of the major aspects of becoming an effective professional within Medical Device Organisations.

When developing the Diploma learning philosophy we understood the importance of flexibility for our students; firstly in the way that they approach study and secondly in the way they can demonstrate achievement of the fundamental body of knowledge.

With this in mind, the modular approach, work based correspondence methods supported by expert tutors and the accreditation of prior learning make this Diploma the most unique learning product within the field of quality assurance and regulatory affairs.

The Diploma itself offers eight core modules to provide the modern medical device professional with the knowledge, tools and techniques needed to manage the many aspects of worldwide medical device quality management and regulatory affairs.

We use blended learning techniques in order to provide you with the practical tools to understand our body of knowledge. Blended learning means that you are able to utilise the resources within your workplace such as the internet, reflecting on meetings and projects as well as having a workbook that focuses your learning through real life. We have personally selected resources that support you and enhance your knowledge.

We appreciate the cost and time constraints that traditional courses requiring travel and accommodation may cause and as a result we decided from a very early stage that our Diploma will be through correspondence.

In order to ensure appropriate support is available to you as a student we assign a tutor who will work with you on your journey offering you support, advice and often the necessary encouragement to complete the various phases of your Diploma modules.

The Diploma Core Modules are:

- **Module 1**  Medical Device Regulatory Frameworks
- **Module 2**  Medical Device Risk Management Design Development and Product Validation
- **Module 3**  Medical Device Clinical Evaluation
- **Module 4**  Medical Device Conformity Assessment – Preparing and Managing Technical Documentation
- **Module 5**  Medical Device Conformity Assessment – Implementing and Managing Quality Management System Processes
- **Module 6**  Medical Device Post Market Surveillance and Vigilance
- **Module 7**  Working with Competent Authorities, Notified Bodies and other Regulatory Stakeholders
- **Module 8**  Management and Behavioural Skills in Quality Assurance and Regulatory Affairs

The Diploma Includes:

- Workbooks
- Case studies
- Exercises
- Knowledge tests
- Key learning points
- Podcasts
- Visual diagrams of models and flowcharts
- Video clips
- Online reference library
- Online tutor support

For more information call +44 (0)1751 432999, email amd@nsf-dba.com or visit www.nsf-dba.com
Key Benefits of the Diploma

- Completion of the Diploma will give you the fundamental knowledge needed in the management of quality assurance and regulatory affairs within medical devices. The Diploma has been written by experts and completion of the Diploma will allow you to demonstrate that you have attained an assessed level of competence within the medical device industry.

- Integrated work based projects and assignments – working as normal counts towards your study. The Diploma allows you to plug and play with projects you have already completed or are planning.

- Access to a medical devices expert for support with assignments and business consultancy for free! Save thousands of pounds on consultancy fees by getting free advice through study.

- Access to an online library of industry leading references and resources. Free instant access to leading QA/RA intelligence when you need it most.

- APL – we recognise your past achievements and give you discount off the cost of the Diploma.

- The price of £5,000 is currently an introductory rate; you get a tailored course for the QA/RA professional for a fair and reasonable price, the Diploma is value for money when compared like for like with other training courses.

Progressing through the Diploma will enhance your technical and management skills and can be used for your own professional development. Figure 1 demonstrates this in further detail.

The Vision for Medical Device Professional Development

Outcomes: Technical expertise. Expert in the industry (i.e. validation specialist, process quality engineer, software quality engineer).


Outcomes: Management professional. Best practice management and leadership (i.e. performance management, project management, leadership).

Outcomes: Medical device professional. Solid base of knowledge gained that is essential for every medical device professional.

Figure 1

For more information call +44 (0)1751 432999, email amd@nsf-dba.com or visit www.nsf-dba.com
**NSF-DBA Diploma**

**Accreditation of Prior Learning (APL)**

**Background**
When developing the Diploma it was important to us that the knowledge you have obtained and training you have already undertaken are used as a basis of the qualification. Therefore we have created a specific model for reviewing your in-house and external training to determine whether or not you qualify for exemptions to the modules.

**Process**
When applying for the Diploma you will be required to identify any specific training that you believe may support your fundamental knowledge of the learning outcomes. We will evaluate the courses in terms of content and contact you to determine your fundamental knowledge and experience. A date will be booked to formally review all of your exemptions and ascertain which modules you will be exempt from, your tailored Diploma will then be processed and your assignments issued.

The assessment process for accreditation of prior learning is thorough and may sometimes require you to demonstrate your knowledge of various updates.

**Typical examples for exemptions are as follows:**
- Medical Device Directive three day external training course delivered via a notified body
- In-house Medical Device GMP/ISO13485:2003 audit course delivered by an internal expert

**Benefits**
- You do not have to study elements in which you have already received foundation knowledge
- You are able to demonstrate your knowledge through the assignments leading to faster completion of the module
- Previous investments in training and development are taken into consideration
- The fees reduce with each exemption

**Outcomes**
- A knowledge of the units you will need to undertake and those that are exempt
- Formal recognition of the previous study you have undertaken

---

**Diploma Fees**

**Full Diploma** – £5000
*Introductory rate – a saving of £1500.
Feas could be reduced if you qualify for any exemptions through our Accreditation of Prior Learning process

**Singular Modules**

Module 1
Standalone – £1000

Module 2
Standalone – £1000

Module 3
Standalone – £1000

Module 4
Standalone – £1000

Module 5
Standalone – £1000

Module 6
Standalone – £500

Module 7
Standalone – £500

Module 8
Standalone – £500

To enrol for the Diploma or to find out more contact us at amd@nsf-dba.com

For more information call +44 (0)1751 432999, email amd@nsf-dba.com or visit www.nsf-dba.com
NSF-DBA Diploma  
Work Based Project

**Background**
The work based project is a unique feature of the NSF-DBA Diploma where you are challenged to apply your learning in practice within your work.

**Process**
Your work based project will depend upon what you have done in the past as well as the challenges you face currently within your organisation. The work based project is usually required to be sponsored by a senior manager within your organisation, although it is accepted that this may not be the case for all students.

**Examples include:**
- Managing the regulatory submission of a new medical device into the market
- Selecting a supplier for a private label
- Managing the regulatory submission
- Managing a major change to either a design feature or a new market
- Ensuring all regulatory and quality aspects are covered
- Preparing and undertaking a significant medical device audit at a corporate location, supplier or on a third party basis (notified body/mock audit)

The work based project will be typical of a scientific/technical report not exceeding 7500 words and is in accordance with international education quality assurance standards. For each work based project you will be assigned a mentor from the NSF-DBA Diploma team.

**Benefits**
- Successful completion of a work based project will allow you to practically apply the knowledge gained in the Diploma to a real scenario within the workplace
- This industry leading learning approach ensures excellent professional development through maximising your learning experience
- You will gain access to a medical device expert within the subject matter area
- Work based project marking is in accordance with international education quality assurance standards to ensure your competence
- You will receive a comprehensive consulting report from an NSF-DBA expert on your work based project which you will be able to utilise within your organisation

**Outcomes**
- You will be able to demonstrate up to date application of the most current and effective thinking in QA/RA for medical devices
- You will demonstrate excellent professional recognition by successfully completing the work based project
- Successful completion of the work based project will ensure your acquisition of the NSF-DBA Diploma
- Successful completion will ensure confidence within your role and, vitally, fully competent throughout the world of medical devices

For more information call +44 (0)1751 432999, email amd@nsf-dba.com or visit www.nsf-dba.com
NSF-DBA Diploma
Written Assignments

Background
After each module you will be required to complete a written assignment for all eight modules, which is a key part of the Diploma. The assignments will allow you to practically apply the knowledge gained from your learning into your work.

Process
At the end of each module you will be provided with a range of questions where you can select the title of the assignment to match your learning needs or work interests.

The NSF-DBA subject matter expert will give you full support and give you comprehensive feedback on each assignment in the form of a detailed consulting report which you can utilise within your organisation.

Examples of Assignments include:
• Communicating with a competent authority, determining classification and conformity assessment route
• Creating and implementing a risk management process for your design department
• Managing a validation project establishing a validation protocol for a medical device process
• Creating supplier selection criteria and approving a sterilisation/packaging supplier

The written assignments will be the same as expected when writing a report for any medical device regulatory body; not exceeding 3000 words and in accordance with international education quality assurance standards.

Benefits
• Successful completion of assignments allows you to practically apply the knowledge in the Diploma gained to a real scenario within the workplace
• This industry leading learning approach ensures excellent professional development through maximising your learning experience
• You will gain access to a medical device expert within the subject matter area
• Written assignment marking is in accordance with international quality assurance standards to ensure your competence
• You will receive a detailed consulting report on each written assignment from an NSF-DBA expert which you can utilise within your organisation

Outcomes
• You will be able to demonstrate up to date application of the most current and effective thinking in QA/RA for medical devices
• You will demonstrate excellent professional recognition by successfully completing each assignment
• Successful completion of each assignment will ensure confidence within your role and, vitally, ensure your competence within the world of medical devices

For more information call +44 (0)1751 432999, email amd@nsf-dba.com or visit www.nsf-dba.com
Please reserve me a place on the course/s below:

<table>
<thead>
<tr>
<th>Tick</th>
<th>Module Number</th>
<th>Title</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>Module 1</td>
<td>Medical Device Regulatory Frameworks</td>
<td>£1000</td>
</tr>
<tr>
<td>☐</td>
<td>Module 2</td>
<td>Medical Device Risk Management Design Development and Product Validation</td>
<td>£1000</td>
</tr>
<tr>
<td>☐</td>
<td>Module 3</td>
<td>Medical Device Clinical Evaluation</td>
<td>£1000</td>
</tr>
<tr>
<td>☐</td>
<td>Module 4</td>
<td>Medical Device Conformity Assessment – Preparing and Managing Technical Documentation</td>
<td>£1000</td>
</tr>
<tr>
<td>☐</td>
<td>Module 5</td>
<td>Medical Device Conformity Assessment – Implementing and Managing Quality Management System Processes</td>
<td>£1000</td>
</tr>
<tr>
<td>☐</td>
<td>Module 6</td>
<td>Medical Device Post Market Surveillance and Vigilance</td>
<td>£500</td>
</tr>
<tr>
<td>☐</td>
<td>Module 7</td>
<td>Working with Competent Authorities, Notified Bodies and other Regulatory Stakeholders</td>
<td>£500</td>
</tr>
<tr>
<td>☐</td>
<td>Module 8</td>
<td>Management and Behavioural Skills in Quality Assurance and Regulatory Affairs</td>
<td>£500</td>
</tr>
<tr>
<td>☐</td>
<td>Full Diploma</td>
<td>Introductory rate – a saving of £1500</td>
<td>£5000</td>
</tr>
</tbody>
</table>

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: 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: Applications from delegates whose companies are based outside of the UK/EU will be outside the scope of VAT.

First Name:  Surname:  
Job Title:  Company:  
Full Site Address:  
Postcode:  
Tel No:  Fax No:  
Email:  

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

Enquire for discounted rates on Accreditation of Prior Learning Review, email jp@nsf-dba.com