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The Journal of David Begg Associates

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To speciate or not to speciate?

Bob Pietrowski examines the pros and cons of identifying environmental isolates to the species level.

David Begg associates

welcome

Looking forward to a successful 2007

Mike Bowsher, Managing Partner David Begg Associates

We hope you had a very enjoyable Christmas break and that you are now looking forward to a challenging but successful 2007.

In pharmaceutical terms, 2007 promises to be an interesting year. Perhaps this year EMEA will finalise its expectations for sterile products manufacture and publish a new version of Annex 1. If they do, be sure that we will tell you about it and provide focussed training on the new requirements.

Similarly, 2007 promises to be the year in which ICH initiatives, particularly Q8, 9 and 10, impact upon our activities and quality systems. Again, when they do you can be sure that we will be there to help you implement cost-effective, compliant systems.

For us, 2007 sees the introduction of five new courses; "Quality Management Systems" to be held in March, three short courses on aspects of sterile products manufacture to be held in June, and a one day course on FDA's final regulations on OOS results to be held in early july – more about this later!

We are also introducing a new venue for our courses – Amsterdam! We are very excited about this and we hope to see you there.

We hope that the coming year will be a success for you. If there is anything we can do to make your year more successful, via training, audits or general consultancy, please do not hesitate to contact us. That's what we're here for!

David Begg associates

Mike Bowsher

Tech Talk

Bob Pietrowski examines the pros and cons of identifying environmental isolates to the species level.

To speciate or not to speciate? That is the question...

Increasingly, we are being encouraged by consultants and regulators to identify environmental isolates beyond the genus level and down to the species level. This involves additional time, resource and expense – and to what end? What additional value does speciation provide to us, to the patient or indeed to the regulators?

Why Do We Identify Environmental Isolates?

Many years ago, a young Quality Control Manager (a Microbiologist) entered the office of the Production Manager with some exciting news. "Guess what!" he said, "We've isolated a very interesting organism from your clean room. It's a species of the genus *Jensenia*. This is a fascinating organism - it's a little like a *Mycobacterium* and a little like *Corynebacterium*. "That's really interesting", said the Production Manager (also a Microbiologist) in a sarcastic voice. "Now, answer me three simple questions; what is the risk associated with this organism, where is it coming from and what do I need to do to get rid of it? If you can't answer these questions, go away and don't come back until you can!"

Suitably humiliated, the young QC Manager went away with his tail between his legs. That young QC Manager was me and it is a lesson I have never forgotten!

We identify environmental isolates for very important, practical reasons:

- To assess the risk associated with the organism
- To establish the most probable origin of the contamination – where it is coming from
- To allow us to devise eradication strategies for the organism – to get rid of it

And additionally…

To allow us to recognise re-isolation of the same organism, either because our eradication strategy has failed or because we have re-introduced the organism into the manufacturing environment.

Is it really necessary to identify isolates down to the species level in order to satisfy these objectives? I believe that in the vast majority of situations, it is not!

The Importance of Colonial Morphology and the Gram Stain

Often, just looking at colonies on an agar plate is sufficient to carry out a sufficient level of identification.

Rough colonies of *Bacillus sp.* are readily recognisable, as are the shiny, white or yellow colonies of *Staphylococcus* or *Micrococcus*. If the colonies are black or green and furry, we know that the organism is a mould; probably either *Aspergillus* or *Penicillium*.

For bacteria, our initial identification can be confirmed by a quick Gram stain. Thus, we can quickly say that the isolate is a Gram positive coccus (probably *Staphylococcus* or *Micrococcus*), a Gram positive rod (*Bacillus*) or a Gram negative short rod (if isolated from water, almost certainly a pseudomonad). This quick and rudimentary identification is sufficient to allow us to:

- Assess risk
- Determine the most probable origin
- Devise eradication strategies
- Recognise re-isolation

Table 1 summarises this information for a range of common organisms.

So why do we need to go further and identify isolates down to species?

People Like Names!

There is a common belief that, if we can put a second name to an organism, suddenly we know much more about it.

If we say we have isolated a *Bacillus* from our environment, our information appears incomplete. However, if we say we have isolated *Bacillus megaterium* from our environment, then we feel we have done a more complete job. But have we? What do we really know about *Bacillus megaterium* that allows us to take more effective action than we would take if we simply knew the organism was a *Bacillus*? The answer is almost certainly nothing! Giving the organisms a second name may give us a warm glow, but it doesn't normally help us to do our jobs better. And what is more, it has taken us several days and expensive equipment to get to this point!

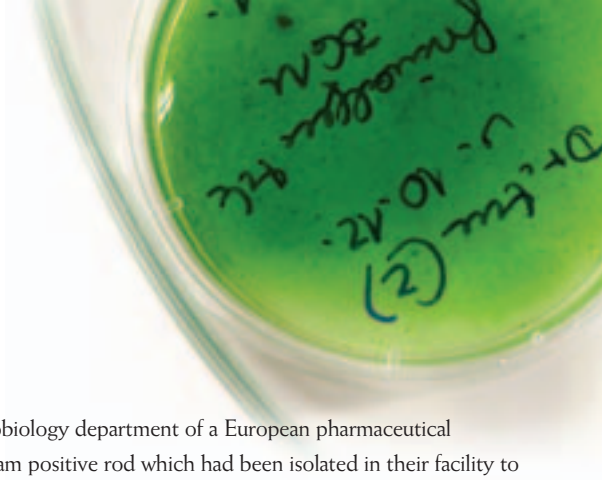
Furthermore, how confident are we in our identification of the organism as *Bacillus megaterium*?

What's in A Name?

Identification is inextricably linked to classification (or taxonomy) and here we are faced with a major problem – the mindset of taxonomists.

Bacterial taxonomists belong to one of two diametrically opposed groups; the

Tech talk



Splitters and the **Clumpers**. Splitters classify organisms on the basis of how **different** they are from other organisms, whereas Clumpers tend to classify organisms on the basis of how **similar** they are to other organisms.

At the moment, the Splitters seem to have the upper hand, so that similar organisms are given very different names which tends to mask family similarities. Thus, what used to be *Bacillus stearothermophilus* is now called *Geobacillus stearothermophilus*. An inexperienced Microbiologist may, wrongly, assume the newly named *Geobacillus* does not share key characteristics with *Bacillus* species. Similarly, organisms that were formerly classified as *Pseudomonas* are now called *Burkholderia* and other weird and wonderful names, but they still share, as far as we are concerned, key characteristics with *Pseudomonas* species and our reaction to them should be essentially the same.

This problem is exacerbated by our attempts to identify organisms using proprietary systems such as API, Vitek, ribotyping etc. These increasingly sophisticated techniques, allied to a classification philosophy which tends to accentuate differences rather than similarities, makes it more likely that identification procedures will produce less clear identification and more likely that the same organism, when put through the same system on two different occasions, will be identified differently on each occasion.

Table 1 Characteristics of Some Common Environmental Isolates

ORGANISM	COLONIAL MORPHOLOGY	GRAM STAIN	RISK	ORIGIN	ERADICATION STRATEGY
BACILLUS	Smooth or rough, white or cream colonies	Gram Positive Rod	Spores highly resistant to killing by heat and disinfectants	Soil, dust, cardboard, wood etc.	Check effectiveness of disinfection of materials and trollies entering area via transfer hatches etc
STAPHYLOCOCCUS	White, cream or yellow domed colonies	Gram Positive Coccus	General contamination risk. Some species toxigenic	Human skin	Check effectiveness of gowning procedures personal hygiene, glove disinfection procedures
MOULDS	White, black or green hairy large spreading colonies	N/A	Spores, although not heat resistant, permit rapid spread of contamination	Soil, dust, cardboard, wood etc.	Check effectiveness of disinfection of materials and trollies entering area via transfer hatches etc
PSEUDOMONAS	Cream or white colonies, sometimes surrounded by greenish pigment in agar	Gram Negative Rod	Endotoxin risk, some species resistant to disinfectants, some toxigenic	Water and moist environments	Remove standing water, check cleaning materials, sanitise water systems

Thus, in Week 1 we may isolate a Gram positive rod from our environment which, upon speciation, is found to be *Bacillus pietrowskiensis*. In Week 2, we isolate a Gram positive rod which we identify as *Bacillus beggii*. Are we really sure that there are in fact two different organisms and not the same organisms misidentified?

And anyway, does it really matter? We have isolated a Gram positive rod from our environment on two consecutive weeks, which tells us that we have a problem controlling *Bacillus* species!

Misidentification or organisms is not uncommon and we would be well advised to treat all identifications with a healthy degree of caution.

Recently, the Microbiology department of a European pharmaceutical company sent a Gram positive rod which had been isolated in their facility to a laboratory of international repute for identification by ribotyping. Several weeks later, the laboratory sent back a report stating that the organism was a species of *Bacillus* which had previously only ever been isolated from fermented Korean seafood! As the product had no links to fermentation, Korea or seafood it is highly likely that the identification was, to say the least, questionable and unhelpful. It also took a lot of time to obtain, as well as a lot of money!

So Is There a Place for Speciation?

There are two major benefits from speciation

- It satisfies regulatory expectations
- It can assist investigation into the origins of organisms and identification or re-contamination incidents.

The regulatory expectation for speciation is clear and cannot be simply ignored. Having said that, I believe that the frequency of speciation should be restricted to incidents when it provides real value.

For example, if a Gram positive rod is isolated form a bulk product or a Sterility Test unit, speciation of the organism and isolates from the manufacturing and testing environments can assist in determining where the contaminant was introduced.

Similarly, speciation of isolates from water samples can assist in determining whether our eradication strategies have been effective.

My advice, though, is not to put too much importance on what is sometimes an unreliable practice.

In Summary

- Don't overestimate the value of speciation – in many cases it does not provide practical value
- Don't underestimate the risk of incorrect speciation, and of inappropriate conclusions drawn therefrom.
- Speciation can slow down your reaction to problems. Don't wait for completion of speciation to instigate corrective actions; you already have sufficient information from Gram stain etc to determine risk, most probable origin and eradication strategies
- Be prepared to defend your practices to regulators, by the use of good science.

Location, Location, Location...

The Marriott Hotel, Amsterdam

For some time now, we've been considering running some of our courses in mainland Europe. It's not that we're unhappy with our venues in the UK and Ireland – far from it – it's more that we feel that we should recognise the fact that most of our delegates come to us from outside the British Isles and make an effort to come to you from time to time.

Having finally taken the decision, it wasn't hard to settle on Amsterdam as a venue. It's a great city with excellent transport links and, next to the British, the Dutch are our biggest customers!

The next step was to find a suitable hotel, and in this regard we have very firm expectations:

- The hotel must be conveniently located for transport, shopping, restaurants and nightlife
- The hotel rooms and services must satisfy the demands of our delegates at a reasonable price
- The facilities for training must meet our exacting standards
- The staff at the hotel must make us and our delegates feel at home and anticipate our needs.

So last summer we spent several days sampling the hotels of Amsterdam; a tough job but someone had to do it!

On paper, many hotels appeared to offer what we were looking for, but in the end one hotel stood head and shoulders above all the others – The Marriott!

The Marriott isn't the prettiest hotel in Amsterdam; maybe some of the others had slightly better restaurant facilities and exercise equipment. But where the Marriott really scored was their staff. Everyone is really helpful and is committed to providing all their guests with a top class service. Also, they realised very quickly that we are not interested in cramming delegates into a training room like sardines – our delegates are our guests and deserve to be treated properly. That's how the Marriott see things too!

The location of the hotel is really good – the main shopping areas are just across the canal in front of the hotel, there are numerous excellent restaurants within 10 minutes walk, joggers can join the hundreds of local runners in the adjacent Vondelpark, (the hotel can provide you with different routes!) and for you Culture Vultures, the world famous Rijksmuseum is a five minute walk away.

We are really excited about our new venue and we look forward to welcoming you to many courses there in the future.

Our popular training course, "Pharmaceutical Quality Risk management" will be held at the Marriott Hotel, Amsterdam from 5 March for four days.

Forthcoming Courses

What's planned for the next five months, March to July 2007

Pharmaceutical Risk Management

Marriott Hotel, Amsterdam, The Netherlands
5 - 8 March 2007

NEW location

Pharmaceutical risk management is the latest "hot topic" in GMP! The FDA have stated that they will use risk assessment in their inspections and expect manufacturers to adopt risk-based quality systems. Furthermore, adoption of ICHQ9, "Pharmaceutical Risk Management" will make it an international GMP expectation. Come and learn what exactly is expected and how to apply risk management techniques to your quality operations. Our very first course in Amsterdam!

Course Fee: £2375.00

Pharmaceutical Formulation & Processing Part 2,

Qualified Person & Professional Development Training
Marriott Hotel, York, UK
12 - 16 March 2007

Second part of this two part module, designed to provide the prospective Qualified Person or pharmaceutical professional with essential knowledge of formulation requirements and key processing methods for the major classes of pharmaceutical dosage forms.

Course Fee £2800.00 Plus VAT

Free Seminar
Qualified Person & Professional Development Training

Marriott Hotel, York, UK
13 March 2007

Interested in becoming a QP? Why not attend this free seminar to find out more about what we can offer. Learn about what is required to become a QP and see one of our training modules in action.

Quality Management Systems

Marriott Victoria & Albert Hotel, Manchester, UK
19 - 22 March 2007

NEW course

This brand new course will provide you with all you need to know to design, implement, monitor and maintain a cost-effective quality management system to current international regulatory requirements. Whether you are a young, start-up company or a global pharmaceutical giant, this course is for you!

Course Fee: £2065.00 Plus VAT

Practical Aspects of Pharmaceutical Validation

Marriott Victoria & Albert Hotel, Manchester, UK
26 - 29 March 2007

This ever-popular four day course will provide you with sound, practical advice on how to organise, document and manage all aspects of qualification and validation to meet international GMP requirements. In addition, validation requirements for specific applications such as cleaning, labelling and packing, sterile products, computer systems and many more will be covered.

Course Fee: £2065.00 Plus VAT

Pharmaceutical Good Manufacturing Practice

Clontarf Castle Hotel, Dublin, Ireland
23 – 26 April 2007

Europe's most popular GMP course! An excellent overview of EU and US GMP regulations and expectations, plus up to the minute guidance on current "hot topics".

Course Fee £2375.00

Pharmaceutical Microbiology

Qualified Person & Professional Development Training
Marriott Hotel, York, UK
14 – 18 May 2007

A comprehensive, five day course providing the prospective QP or technical professional with all they need to know about microorganisms, the threat they can pose to product quality and patient safety, how to implement an effective microbiological control strategy and how to assess microbiological risk.

Course Fee £2800.00 Plus VAT

Engineering Aspects of GMP

Marriott Victoria & Albert Hotel, Manchester, UK
4 – 7 June 2007

This highly popular course is designed to provide engineering staff with the knowledge to apply GMP principles to their work and to provide QA staff with an understanding of the special challenges faced by engineering staff.

Course Fee £2065.00 Plus VAT

Effective Pharmaceutical Audits and Self-Inspections

Marriott Victoria & Albert Hotel, Manchester, UK
4 – 7 June 2007

Learn how to carry out audits with skill and sensitivity, whilst ensuring that you do not overlook important issues. This course will help you to make your audits really value adding.

Course Fee £2065.00 Plus VAT

Book online at www.david-begg-associates.com

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Active Pharmaceutical Ingredients

Qualified Person & Technical Development Training

Maryborough House Hotel. Cork, Ireland
18 – 22 June 2007

This course will provide you with all you need to know about the application of GMP to the manufacture and control of APIs and bulk biologicals. The course includes visits to a state of the art API manufacturer and one of the largest biotech plants on Europe.

Course Fee £3151.00

Deviation Reporting and CAPA

Clontarf Castle Hotel, Dublin, Ireland
19 -20 June 2007

This two day course is designed to provide you with the tools and skills to identify, correct and report the root cause of quality problems quickly and efficiently so that you can demonstrate that your CAPA systems work!

Course Fee £1405.00

Key Topics in Sterile Products Manufacture

NEW course

A Practical Interpretation of Annex 1

Marriott Victoria & Albert Hotel, Manchester, UK
25 June 2007

A short course designed to bring you up to date on the latest requirements of Annex 1 of the EU GMP Guide and, more importantly, how to comply in a practical, cost-effective way.

Course Fee £630.00 Plus VAT

Environmental Monitoring

NEW course

Marriott Victoria & Albert Hotel, Manchester, UK
26 – 27 June 2007

This course is designed to help you to understand the methodologies of environmental monitoring, how to use them to design a comprehensive, targeted monitoring programme and how to act upon the results to assure real control.

Course Fee £1195.00 Plus VAT

Process Simulations

NEW course

Marriott Victoria & Albert Hotel, Manchester, UK
28 June 2007

A short course designed to ensure that your process simulations (broth fills) comply with current EU and US requirements. We will also tell you how to deal with problems arising from process simulations.

Course Fee £630.00 Plus VAT

Management of Contract Services

Marriott Victoria & Albert Hotel, Manchester, UK
2 – 5 July 2007

More and more companies are choosing to put activities and services out on contract rather than perform them in-house using company personnel. This course is designed to explain EU and US regulations for the management of contract services and to provide practical guidance on exactly how to achieve maximum efficiency and compliance.

Course Fee £2065.00 Plus VAT

Handling OOS Results

Marriott Manchester Airport Hotel, Manchester, UK
5 July 2007

NEW course

A clear guide to FDA's final guidance on handling OOS results, including what the regulation covers and how to design practices and procedures which ensure compliances.

Course Fee £630.00 Plus VAT

Role and Duties of the Qualified Person

Qualified Person & Technical Development Training

Marriott Hotel, York, UK
9 – 11 July 2007

This course provides essential guidance not just on the legal duties of the Qualified Person, but also on how the QP should organise themselves, their colleagues and the quality system to ensure that they fulfil their duties with skill and professionalism in the best interests of the patient and their employer.

Course Fee £1710.00 Plus VAT

Get in touch now to book your place on any of these courses

Call us on +44 (0) 1751 432999 or email: courses@david-begg-associates.com

Industry News

Q10 Guideline Progressing Well

The ICH working party for guideline Q10, Pharmaceutical Quality Systems, have agreed a new, detailed draft document, Version 9.1

This latest draft is well written and comprehensive – it cannot be too far away from the finished article!

It consists of five sections:

- Pharmaceutical Quality System
- Management Responsibility
- Management and Continual Improvement of Product Quality
- Management and Continual Improvement of the Pharmaceutical Quality System
- Glossary

Pharmaceutical Quality System

The opening section clearly states the objective of the guideline, which is to establish a model for an effective quality management system for the pharmaceutical industry, which:

- Ensures the realisation of a quality drug product
- Establishes and maintains a state of control
- Facilitates continual improvement over the product lifecycle

It also clearly states that the guideline is intended to complement, not replace, existing Good Manufacturing Practices. It seeks to act as a bridge between different regional regulations and thus help industry and regulators to achieve harmonisation of a lifecycle approach to qualify systems.

The section also emphasises key system elements and design considerations such as:

- The key role of Quality Risk Management approaches
- The relatively new concept of Knowledge Management over the product lifecycle
- The value of periodic monitoring on the system
- The importance of key performance indicators
- The central role of change management and CAPA

It also stresses the importance of documentation of the system and recommends the creation of a Quality Manual or equivalent.

The guideline puts emphasis on technology transfer – something which the traditional GMPs have largely overlooked.

Of particular interest is the importance given to the relatively new concept of Knowledge Management, ensuring that knowledge gained during the development phase is effectively passed on to production, and so on. The maintenance of this knowledge base throughout the product lifecycle is crucial and represents an important contribution to quality management thinking by the working party.

Management Responsibility

Like ISO 9000 and all the GMP regulations, this document stresses the importance of the commitment of management to quality, but unlike these other documents, the draft guideline provides detailed recommendations for precisely how this management commitment should be realised. Thus, the document addresses management's role: in:

- Endorsing the quality policy
- Assigning responsibilities for oversight of the total system
- Ensuring effective planning
- Providing the necessary resource
- Ensuring that the system is effectively communicated
- Reviewing the system for continuing suitability and effectiveness

Management and Continual Improvement of Product Quality

This section describes four systems elements which, building upon existing GMP requirements, help to create a coherent quality management system which covers the entire lifecycle of a product – from Pharmaceutical Development through to product discontinuation. These are:

- Process and product quality monitoring system
- Corrective action and preventative action (CAPA) system
- Change management system
- Management review of product quality

Each of these is discussed in some detail.

Management and Continual Improvement of the Pharmaceutical Quality System

As well as continually improving the quality of our products, it is essential that we continually improve our quality system, and this is clearly recognised in the draft guideline.

Thus, it stresses the importance of setting key performance

indicators to monitor the effectiveness of the system and of being responsive to external factors such as changes in regulations and technical innovations.

We recently spoke to Gerry Migliaccio of Pfizer, who heads the Q10 working party. He is very enthusiastic about the degree of unanimity between the group members regarding the scope and content of the guideline. We are not surprised – this potentially represents a positive contribution to quality thinking which will assist the industry and regulators to set a meaningful framework for the way we manage quality.

The latest developments on Q10 will be discussed during our training course "Quality Management Systems" to be held in Manchester from 19 to 22 March 2007. This course is designed to help pharmaceutical companies of all sizes to design, implement and operate a cost-effective Quality Management System to meet all regulatory expectations.

ICH Q9, Quality Risk Management – EU Implementation

ICH Q9 reached step 4 of the ICH process in November 2005. EMEA then published a notification of its approval and a link on their website in January 2006.

By the end of 2006 both Japan and the USA had adopted ICH Q9 into their regulatory processes but, unfortunately, the EU still had not. The EMEA has had a Q9 Implementation Group consisting of inspectors and regulatory assessors working to determine the best strategy for adopting Q9 in the EU. It is hoped that the EU adoption of Q9 will occur after the meeting of the Inspectors Working Group in February 2007. It is anticipated that the implementation will include the following:

- The guide is likely to be issued as an Annex of the EU GMP Guide but it will be made clear that the use of the Q9 approach to Quality Risk Management is optional.
- The 'Introduction' and Chapter 1, Quality Management, of the EU GMP Guide will be revised to include references to quality risk management.
- Some CHMP Notes for Guidance to MA Applicants will also be revised to include reference to quality risk management.

EU News
New Draft Annex 3 – Radiopharmaceuticals

In September 2006, the European Commission issued a new draft Annex 3, manufacture of Radiopharmaceuticals.

The Annex provides guidance for some relatively new technology, in particular Positron Emission Tomography (PET). This process often involves very short lived radionuclides and these present a challenge to the normal release processes for medicinal products. Some of these radionuclides have a shelf life of hours and therefore the active ingredient is synthesised, made into a dosage form and administered, in less than one working day.

For sterile products, the Qualified Person release is still required, but there will be a two stage process – releasing the product for administration and finally releasing the product after sterility testing. Guidance is given as to the GMP and non-GMP parts of the process. For example, cyclotron and reactor steps are regarded as non-GMP, with GMP coming into force as soon as this chemical synthesis starts.

Briefly the principle changes proposed are:

- Risk assessment is emphasised
- Parametric release is (still) seen as necessary, as are systems to follow up in the event of failed result when all testing has been completed.
- Paragraph 29, which refers to environmental conditions for sterile radiopharmaceuticals produced in closed and automated systems is badly written and is likely to be the most contentious; it specifies Grade C whereas the previous requirement was Grade D. In practice many manufacturers already have Grade C.

Industry have until the end or March 2007 to comment on this draft.

The latest developments on Q10 will be discussed during our training course "Quality Management Systems" to be held in Manchester from 19 to 22 March 2007.

What were the QP students HOLDING?

Since we published the photograph of the Qualified Person students completing their training with us in the last issue of the Journal, we have received numerous emails asking what they were holding.

We believe that Qualified Person training represents an important period in any pharmaceutical professional's career and so we provide everyone who studies four or more modules with us a permanent memento of their time with us – an individually engraved mortar and pestle.

Students tell us they are proud to display them in their offices, where they constitute an interesting conversation piece.

Students tell us they are proud to display the mortar and pestle in their office, where they constitute an interesting conversation piece

We also provided the gifts to all the Pfizer US quality professionals who underwent in-house QP-like training with us in 2005 and 2006. They too display their mortar and pestles with pride!

It may seem strange that a US company should wish to put its staff through European QP style training, but several companies in North America have recognised the benefits of the structured training that the QP syllabus represents, and also the advantages to be gained from having staff in their US manufacturing sites who can act as the "eyes and ears" of the Qualified Person in

Several companies in North America have recognised the benefits of the structured training

Europe to liaise technically and professionally on GMP and quality issues, in line with the expectations of Annex 16.

Back to Europe…the mortar and pestle are not the only additional offering we provide for our QP students. We strongly believe that QPs require much more than technical knowledge to act effectively; they must be skilled team builders, communicators, negotiators and report writers. That is why we provide, free of charge, evening tutorials designed to improve the delegates' "soft skills" and truly prepare them for what awaits them. The delegates find these sessions especially valuable and readily give up their free time to attend.

We also provide a personal tutor to each of our "core" students. The tutor, one of the DBA Partners, meets with the student regularly and gives guidance on important issues such as where

AT LAST! A qp reunion

As we mentioned in the last issue of the Journal, we have at last reacted to popular demand by former QP students and arranged a two day reunion meeting at the Hilton Hotel, York, on Thursday and Friday 12 and 13 July 2007.

Over the two days we will provide CPD training sessions on current and emerging legislation and "hot topics" for practising QPs. We hope to get former QP students to provide many of the talks as we know that you learn much more from each other than you do from us!

As well as the formal sessions, there will be evening entertainment to allow people to re-live their QP student days and to re-establish old friendships.

To date, over 60 former students have indicated their intention to attend. If you are interested in joining us and have attended at least four QP training modules, please contact Stella Pearson-Smith at our offices.

QPs must be skilled team builders, communicators, negotiators and report writers

additional study might be required, how to gain the necessary practical experience, professional body membership and preparation for the QP assessment interview. The tutor therefore provides valuable support, both to the student and the student's sponsor.

If you would like to benefit from the extra services we offer to our QP students, why not contact Stella Pearson-Smith at our offices. You can join the QP training at any time and we will help you to decide how many modules you need to attend and where additional study won't be necessary.

Please call or email – we're here to help.

DBA People

Hooked!

In each Journal we spotlight a member of the DBA team so that you can get to know us better. In this issue it's Mike Bowsher.

Some of us like fish to eat, whilst others prefer fish to catch! When not at the helm of DBA, Mike Bowsher spends some of his leisure time indulging his passion for fishing – mostly salmon fishing in Scotland around the River Tay and its tributaries.

Son Neil was the inspiration for Mike to start. He went on many fishing trips with Neil watching him expertly cast his line. Rather than "sit around" just watching he decided to try his hand at fly fishing during a family holiday in Devon – and the bug bit.

Mikes love of fly fishing has been developed and honed to a fine art – with just a little help and advice from Neil. He is very proud of his first salmon, weighing some 9 lbs, taken on the River Tay some years ago.

At the present time, Mike has only fished in the UK, but is increasingly tempted (probably by the "fishy stories"!) to try further a field. So the likes of Canada, Alaska, Norway or Iceland all beckon – as time now permits!

Mike has also done some trout fishing, mostly around North Yorkshire. His most memorable catch was 30 fish in one afternoon – this was due to a flash flood two years ago when thousands of trout escaped from local fish farms. However, Mike is adamant that this is definitely NOT real fishing!

Salmon fishing is a difficult business, calling for lots of patience in the long (sometimes very long!) gaps between bites. However, as Mike explains, nothing can prepare you for the excitement of that wonderful moment of the first real pull or take on the line when the adrenaline really flows.

Often the fight with the salmon is an exhausting experience (and a battle of wills with the wily salmon). On one occasion the fish almost hauled Mike head first into the river. A call for rapid assistance to someone on the river bank didn't help – apparently said "gentleman" was of the anti-fishing persuasion. So escaped perhaps one of the biggest salmon Mike might have landed!

As Mike explained, there are many and varied factors which affect the success of salmon fishing. For example, the general conditions of the river (flow, height, visibility), weather, temperature, light and, not least, the time of year. Local knowledge is also vital and a little time spent researching this can pay dividends – not to mention the advantage of striking up a good relationship with the local Gillie!

One of Mike's favourite spots is the beat near Scone Palace on the River Tay. His best catch was 8 salmon in 3 days (including one of 11 lbs), some of which were brought quickly back to North Yorkshire, where they were smoked locally. Anyone who has eaten smoked wild salmon will know that the taste and texture is far superior to that of farmed salmon.

Mike looks forward to enjoying increasing time to allow his "fishy business" to flourish further.

MIKE SUITABLY INSPIRED BY HIS FIRST SALMON

Congratulations to:

in the past four months, DBA has helped the following people obtain QP status:

Matthew Jaynes, Penn Pharmaceutical Services Ltd, UK; Joanne Lewis, GE Healthcare Ltd, UK; Chris Miller, NPIL Pharmaceuticals Ltd, UK; Gill Morris, Baxter Healthcare Ltd, UK; John O'Neill, formerly with Nicobrand, UK; Colin Newbould, Essential Nutrition Ltd, UK; Jenni Newcombe, Actavis UK Ltd.

In the next DBA Journal.

Industry News as ever, we search for regulatory changes so you don't have to, Tech Talk setting key performance indicators for your Quality Management System. Location, Location, Location…the Hilton Hotel, York. DBA People an obsession with wildlife. Forthcoming Courses – a review of our training courses for Spring and Summer 2007.

If you have any comments or suggestions for the next issue of the Journal, please email us at journal@david-begg-associates.com

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