DBA

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The Journal of David Begg Associates
Issue 1 Autumn 2005

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David Begg associates

welcome

to the new DBA Journal

Mike Bowsher,
Managing Partner
David Begg Associates

A very warm welcome to this the new David Begg Associates Journal which we are very excited about and we hope you will enjoy. The purpose of the Journal is to keep all of our clients abreast of upcoming David Begg Associates courses as well as keeping you informed about industry developments.

In addition we intend to bring you interesting articles, industry news and stories on those who have attended our courses or are part of our hardworking team here in Kirkbymoorside. For this issue, Pete Gough highlights some of the new developments in our highly regulated and fast moving industry, in Tech Talk we compare EU and US Clean Rooms and we give you the chance to register your interest in one of our upcoming new courses.

Thank you for your feedback

As you may know, we carried out an extensive market research study in the Spring, where we spoke to thousands of our customers about what they both liked and disliked about David Begg Associates and our courses. The response to the research was fantastic and we heard some very interesting opinions, some of which were very positive and some made us realise we still have room for improvement. In this Journal we tell you about some of your opinions and what we're doing to get better and keep you happier with us.

One of the issues we have addressed since we carried out the market research is to introduce new training course venues chosen not only for their superb facilities but also their proximity to major road, rail and air links to make the journey to and from a David Begg Associates course as quick as possible – wherever you're coming from.

From strength to strength

2006 is a landmark year for David Begg Associates as we shall celebrate our 20th anniversary. The Partnership was formed in 1986 and originally operated from a single room. Through hard work and training excellence the company has grown to where it is now – the market leading pharmaceutical training company employing 26 people from our headquarters in Kirkbymoorside near York.

But we will not be resting on or laurels in our anniversary year; we are making some very exciting and challenging changes which will benefit you, our clients.

One important change we're making is the way in which we communicate with you. Many of you told us that in the past we sent out too much mail, so now all that is about to change. From now on we will be advising you of courses in the following way:

Training Course Programme: Annually
DBA Journal: Every 4 months
Course brochure: 12-15 weeks prior to courses
Course email: 5 weeks prior to each course

We need your help

To help us with this communications plan it is important that we know your current email address. On the reverse of the letter which accompanies this Journal you'll find a fax-back form which allows you to quickly and easily let us know your up to date details.

I hope you enjoy this issue of the Journal, we'd love to hear your opinion of it or suggestions as to what you'd like to see in it in future.

Congratulations to: in the past six months, David Begg Associates has helped the following people obtain QP status:

Gareth Adlam, 3M Healthcare Ltd. **Samantha Clack**, Eli Lilly & Co. Ltd. **Marcus Evans**, Fuchs Lubricants (UK) plc. **Mark Girdwood**, Bio Products Laboratory. **David Ling**, AstraZeneca Pharmaceuticals.

Industry News

with DBA's Pete Gough

Directive 2004/27/EC – Are You Auditing Your API Suppliers?

Directive 2004/27/EC comes into force from 30 October 2005. Among the many changes arising from this directive is the requirement for active pharmaceutical ingredients (APIs) to be made in accordance with GMP (as described in Annex 18 of the EU GMP guide) and for manufacturers of medicines to declare that their APIs have been made in compliance with GMP. EMEA guidance states…

"It is expected that the holder of the manufacturing authorisation will base such a declaration on carrying out, or having carried out on his behalf, an audit of the manufacturers/distributors of the active substances concerned. Examination, by inspectors, of the audit programmes used by authorisation holders for conducting regular audits (every 2 – 3 years), including review of audit reports, is one of the primary means by which Competent Authorities will determine if manufacturing authorisation holders are in compliance with the above articles."

Thus, from 30 October 2005, all manufacturers of medicinal products are required by law to audit all their API suppliers on a regular basis and inspectors will review audit reports to ensure that you are complying with the law.

Do you have an audit plan in place? Do you have auditors who are qualified to carry out audits against Annex 18? If not, you are vulnerable to regulatory criticism.

David Begg Associates is holding a four day training course entitled "Auditing the API Manufacturer" in Cork, Ireland from 13 to 16 February 2006. The course will include a visit to a modern API manufacturing facility.

Risk Based GMP – The New "Hot Topic"

During the panel discussion periods on our training courses, we are often asked by delegates "What will be the next "hot topic" in global GMP?" There is no doubt that, right now, it is risk based GMP and risk management.

This emphasis on risk began in the USA when dialogue between FDA and several major pharmaceutical manufacturers on why facilities and quality management systems had failed to evolve significantly since the 1970's led directly to the FDA's 21st Century GMP initiative, launched in August 2002. A stated objective of this initiative is to improve public health by focussing cGMP requirements on potential RISKS by concentrating on aspects of manufacturing which pose the greatest risk. It is thus FDA's stated intention to spend less regulatory effort on low risk products and processes. At the same time, FDA expects manufacturers to understand the risks associated with their own products and processes and design their quality management systems to focus on known areas of risk and to use risk assessment when assessing problems and failures.

The FDA initiative was picked up and built upon by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), and resulted in the preparation of guideline Q9, "Quality Risk Management".

ICH Q9 defines Quality Risk Management as "a systematic process for the assessment, control, communication and review of risks to the quality of the drug product across the produce life cycle." It is about knowing our processes, identifying what is truly important and focussing our money, time, energy and people on those things which have the potential to impact on patients. One could argue that pharmaceutical manufacturers have always striven to do just this, but we haven't always been encouraged to do so by some regulators. Also we have lagged behind many other industries in adopting formal risk management practices; for example the engineering industry has long used Failure Mode Effects Analysis (FMEA) and Hazard Operability Analysis (HAZOP), the food industry has used Hazard Analysis of Critical Control Points (HACCP) and the medical devices industry has used ISO 14971.

ICH Q9 outlines the key stages of risk management…

- risk assessment
- risk control
- risk communication
- risk review

and describes the risk management tools which can be used (FMEA, HACCP, etc). For each tool it provides a short description of its potential use in pharmaceutical quality management.

It is clear that adoption of the principles of quality risk management provides a foundation for science-based decisions, more informed decisions and can provide regulators with greater assurance of a company's competence. It may, therefore, affect the extent of direct regulatory oversight of the company.

Not surprisingly, regulatory bodies worldwide have welcomed ICH Q9 and are actively seeking to build it into national GMP requirements. EMEA intend to incorporate it as an Annex to the EU GMP guide when it is finally approved. In the not-too-distant future, it is probable that manufacturers will be asked during inspections to describe their policy and procedures for risk management. Those companies without coherent, defined systems can expect a hard time from inspectors.

David Begg Associates is hosting a four day training course entitled "Pharmaceutical Risk Management" in Manchester from 20 to 23 March 2006.

Peter Gough MSc, CSci, CChem, FRSC, FIQA

A chemist by training, Peter has over 30 years experience of pharmaceutical manufacture, control and quality management, culminating in the role of Senior Quality Consultant in Eli Lilly's Global Quality Systems division. Peter was until recently a member of the European Federation of Pharmaceutical Industry Association (EFPIA) Manufacturing and GMP ad hoc group and EFPIA topic leader on the ICHQ9 Expert Working Group which prepared the guideline on Quality Risk Management.

Forthcoming Courses

What's planned for the next six months, October 2005-March 2006

Pharmaceutical Good Manufacturing Practice
Moat House Hotel, York, UK
3 – 6 October 2005
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 £1,795.00 Plus VAT

Pharmaceutical Legislation Update
Manchester Airport Marriott Hotel, UK
11 October 2005
Continuing professional development for Qualified Persons and other technical personnel. You will learn about current and proposed changes to legislation and GMP requirements in EU and USA and their impact on QPs and technical managers.
Course Fee £570.00 plus VAT

Pharmaceutical Law and Administration
Qualified Person & Professional Development Training
Castle Hotel, Windsor, UK
17 – 21 October 2005
All the prospective Qualified Person or pharmaceutical professional needs to know about EU, UK and US pharmaceutical legislation and regulatory bodies. This course provides the depth of knowledge and understanding you really need to act in a professional capacity in a highly regulated industry.
Course Fee £2,725.00 Plus VAT

Effective Documentation of Validation Studies
Manchester Airport Marriott Hotel, UK
19 October 2005
A course designed to help you prepare effective compliant documents for all aspects of validation studies from the Validation Master Plan through the User Requirement Specification and Functional Specification, IQ, OQ and PQ protocols and reports to the Validation Summary and revalidation documents.
Course Fee £570.00 Plus VAT

Good Autoclave Practice
Clontarf Castle Hotel, Dublin, Ireland
1 – 3 November 2005
A comprehensive course on the practicalities of autoclave selection, cycle design, cycle validation, equipment qualification, ongoing performance monitoring and management. You will learn current regulatory expectations for steam sterilisation, how to qualify and validate autoclaves effectively, how to trouble shoot problems and best industry practices for monitoring and management of autoclaves.
Course Fee £1,615.00

Chemistry and Pharmacy Registration Requirements
Moat House Hotel, York, UK
7 – 10 November 2005
Run in conjunction with Regulatory Resources Group, this course is designed to provide you with a clear understanding of technical data requirements for EU and US registration submission and subsequent manufacture.
Course Fee £1,795.00 Plus VAT

Analysis and Testing
Qualified Person & Professional Development Training
Moat House Hotel, York, UK
14 – 18 November 2005
A five day course covering the scientific basis for the major analytical techniques used in our industry, allowing you to understand why we select certain types of analysis for specific applications and validation requirements for them. In addition, the course will explain current EU and US GMP expectations for the Quality Control laboratory.
Course Fee £2,560.00 Plus VAT

Deviation Reporting and CAPA
Clontarf Castle Hotel, Dublin, Ireland
22 – 23 November 2005
A two day course designed to help you to identify, correct and report the root cause of any quality problem in an effective and compliant manner. In addition, the course will provide practical advice on the implementation of corrective and preventative action (CAPA) plans.
Course Fee £1,250.00

Batch Record Review and Product Release Procedures
Clontarf Castle Hotel, Dublin, Ireland
24 November 2005
Sound, practical advice on how to meet EU and US regulatory requirements for batch record review and product release, including; how to design records which are simple and easy to use best practices for batch record review and subsequent follow up actions how to speed up the release process and shorten lead times
Course Fee £650.00

The A-Z of Pharmaceutical Water Systems
Moat House Hotel, York, UK
28 November – 1 December 2005
This four day course will provide you with up to date information on EU and US regulatory expectations for water systems and practical advice on system design and validation, maintenance, monitoring and management of systems as well as trouble shooting and risk assessment. In short, all you will ever need to know about water systems!
Course Fee £1,795.00 Plus VAT

Good Documentation Practices
Manchester Airport Marriott Hotel, UK
6 – 7 December 2005
This course is essential for anyone wishing to make their documentation system more efficient, cost effective, user friendly and compliant with EU and US GMP requirements. The course will be highly participative – you will design key documents and perfect your document writing skills.
Course Fee £1,065.00 Plus VAT

Pharmaceutical Packaging
Qualified Person & Professional Development Training
Hilton Hotel, York, UK
23 – 27 January 2006
All the prospective QP or pharmaceutical professional needs to know about packaging materials, pack design, major packaging processes and GMP expectations for packaging materials and packaging operations.
Course Fee £2,630.00 Plus VAT

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

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Sterile Products Manufacture

Clontarf Castle Hotel, Dublin, Ireland
30 January – 2 February 2006

A comprehensive, four day course on the latest EU and US GMP requirements for sterile products manufacture and practical advice on how to ensure compliance in a cost effective and scientifically sound way.

Course Fee £2,240.00

Product Reviews

NEW course

Radisson Edwardian Hotel, London Heathrow, UK
7 February 2006

Chapter 1 of the EU GMP guide is being changed to include a requirement to carry out periodic reviews of all medical products. This course will provide you with clear guidance on what to do to comply with this new legislation.

Course Fee £595.00 Plus VAT

Ongoing Stability Testing

NEW course

Radisson Edwardian Hotel, London Heathrow, UK
8 February

Chapter 6 of the EU GMP guide is to be changed to include a requirement to carry out ongoing stability testing of all medical products. This course will provide you with all the information you need to put in place a compliant, cost effective stability testing programme for your products.

Course Fee £595 Plus VAT

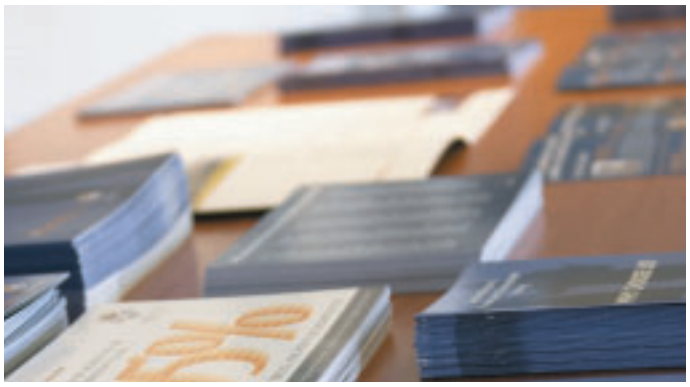
Auditing The API Manufacturer

NEW course

Maryborough House Hotel, Cork, Ireland
13 – 16 February 2006

Adoption of directive 2004/27 means that from October 2005, manufacturers of medicinal products must ensure that their API's are being manufactured to GMP. One important way of gaining this assurance is to audit the manufacturer. This course will provide you with all you need to know to conduct an effective audit. The course includes a visit to an API manufacturing facility.

Course Fee £2,115.00



Cleaning Validation

Manchester Airport Marriott Hotel, UK
28 February – 1 March 2006

This ever-popular course will provide you with what you need to be able to design, execute and audit cleaning validation studies to current EU and US expectations. There will be industry case studies on validation experiences for API's, biotech products and solid dosage forms.

Course Fee £1,130.00 Plus VAT

Quality Management Systems

Qualified Person & Professional Development Training

Marriott Hotel, York, UK
13 – 17 March 2006

A comprehensive, five day course designed to teach you all you need to know about the philosophy and practice of quality management. In addition to providing key guidance of the design, implementation, monitoring and review of a pharmaceutical quality system the course will provide training on the management skills required by a pharmaceutical quality professional.

Course Fee £2,630.00 Plus VAT

Free Seminar for Prospective Qualified Persons

Marriott Hotel, York, UK
14 March 2006

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.

Pharmaceutical Risk Management

NEW course

Marriott Victoria & Albert Hotel, Manchester
20 – 23 March 2006

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.

Course Fee £1,945.00 Plus VAT

Effective Pharmaceutical Audits and Self-Inspection

Hilton Hotel, Cobham, UK
27 – 30 March 2006

Learn how to carry out audits and self-inspections 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. In addition you have the opportunity to become a DBA certified auditor.

Course Fee £1,945.00 Plus VAT.

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

Call us on +44 (0) 1751 432999

email: courses@david-begg-associates.com

DAVID BEGG ASSOCIATES 20 YEARS PROFESSIONAL EXCELLENCE 1985-2005

Course details and prices are correct at the time of printing and are published in good faith.
DBA reserves the right to make any change which may become necessary.

Tech Talk

Pharmaceutical Clean Rooms:

A Comparison of EU and US Expectations

Any pharmaceutical company manufacturing sterile products for the EU and the USA faces a challenge in understanding the different requirements and expectations for clean rooms in these two very important markets and in integrating these expectations into a single, coherent operating standard that is scientifically sound and compliant. This article is intended to help you to achieve both these objectives by comparing and contrasting EU and FDA expectations.

It is important to remember that the original clean rooms and clean room standards were not developed in the pharmaceutical industry but in the micro-electronics and aerospace industries. For this reason, our starting point in this review of EU and FDA expectations is a brief overview of the current ISO standard for clean rooms.

ISO 14644 : An International Standard for Clean Rooms

ISO 14644 is an international standard for clean rooms and controlled environments. It is intended to provide guidance and expectations for the design, construction, classification testing and operation of clean rooms for any application and is thus not specific to the pharmaceutical industry, although it is referenced in Annex 1 of the EU guide to GMP and in the FDA's latest aseptic processing guidelines.

Based on a Japanese standard, it is very flexible and allows classification on the basis of any particle size from 0.1 to 5 microns. The flexibility of this system is very useful for engineers in a wide variety of industries, but inevitably the system will be compared back to the original clean room standard, US Federal Standard 209. The equivalencies are:

ISO	Fed Std	ISO	Fed Std
1	No equivalent	6	1,000
2	No equivalent	7	10,000
3	1	8	100,000
4	10	9	No equivalent
5	100		

EU Standards for Pharmaceutical Clean Rooms

Environmental expectations for sterile products manufacture in the European Union are defined in Annex 1 of the European Guide to GMP. The Annex recognises four grades of controlled environment, A, B, C and D, and quotes particulate and microbiological expectations for each.

Standards for particles are generally given for both the "at rest" and "in operation" conditions. At rest standards should be restored after a short "clean up" period of 15-20 minutes following operation. Particulate expectations at rest and in operation for a Grade A environment, which is normally a unidirectional air flow area, are identical. For Grade D no specification is given in the "in operation" condition, since the level of particulates likely to be present is too high to be meaningful.

Requirements are specified for both 0.5 and 5 micron particles. The previous requirement for zero 5 micron particles in Grade A or Grade B (at rest) has now been modified to a limit of 1/m3, although it is noted that "these areas are expected to be completely free from particles of size greater than or equal to 5μm". This is a clear anomaly to the ISO standard which specifies a limit of 29/m3 for 5 micron particles for ISO 5, although the limits for 5 micron particles in Grades C and D are in reasonable agreement with the ISO formula.

Microbiological contamination levels are specified only in the operational condition and using a variety of techniques. However, this raises a number of issues. For example...

- The limits for microbiological standards are identified as "average values". Should this be an average of one batch-related group of samples, average per day, per week or what? If these are the averages, what is an acceptable upper limit? (In other words, what represents reasonable control?)
- The tables quote figures for volumetric air sampling, settling places, RODAC plates and sampling of gloved hands. Does this mean that the manufacturer is obliged to use all monitoring methods on all occasions?

Table 1. A Comparison of EU and US Environmental Expectations for Pharmaceutical Clean Rooms

COUNTRY	GRADE/CLASS	AT REST		IN OPERATION						
		PARTICLES		PARTICLES		MICROBIOLOGICAL CONTAMINATION				
		MAXIMUM PERMITTED NUMBER OF PARTICLES PER M[a] EQUAL TO OR ABOVE		MAXIMUM PERMITTED NUMBER OF PARTICLES PER M[3] EQUAL TO OR ABOVE		AIR SAMPLE CFU/M[3]	SETTLE PLATES (DIA 90MM) CFU/4H	CONTACT PLATES (DIA 55MM) CFU/PLATE [b]	GLOVE PRINT 5 FINGERS CFU/GLOVE [b]	MASK/ BOOTS/ GOWN [b]
		0.5μ	5μ	0.5μ	5μ					
EU	A	3,500	1	3,500	1	<1	<1	<1	<1	-
USA	100	-	-	3,520	-	1 [a]/3[b]	1	3	3	5
EU	-	-	-	-	-	-	-	-	-	-
USA	1,000 [b]	-	-	35,200 [b]	-	7 [a/b]	3	-	-	-
EU	B	3,500	1	350,000	2,000	10	5	5	5	-
USA	10,000 [b]	-	-	352,000 [b]	-	10 [a]/20 [b]	5	5 /10 [c]	10	20
EU	C	350,000	2,000	3,500,000	20,000	100	50	25	-	-
USA	100,000	-	-	3,520,000	-	100 [a/b]	50	-	-	-
EU	D	3,500,500	20,000	NOT DEFINED	NOT DEFINED	200	100	50	-	-
USA	-	-	-	-	-	-	-	-	-	-

[a] FDA guidelines limit, [b] USP limit, [c] Surfaces and floors

US Standards for Pharmaceutical Clean Rooms

Environmental requirements and expectations in USA quoted here are derived from guidance to be found in three distinct documents…

- **Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing, Current Good Manufacturing Practice, September 2004**
  This is the long awaited revision to the 1987 aseptic processing guidelines and is generally line with EU expectations.
- **Draft document 21 CFR 212, Current Good Manufacturing Practice in Manufacture, Processing, Packing or Holding of Large Volume Parenterals, 1976**
  This document was never ratified or formally adopted. It is however the only source of guidance on expectations for the manufacture of terminally sterilised products and has influenced FDA thinking.
- **United States Pharmacopoeia <1116> Microbiological Evaluation of Clean Rooms and Other Controlled Environments**
  This "informational chapter" was developed by the USP to provide more guidance on microbiological standards for clean rooms.

As in Europe, four different room classifications are commonly recognised in the USA, but these are not equivalent to the European grades. The four classes of clean room are Class 100, 1,000, 10,000 and 100,000. These classifications are based upon the maximum permitted number of particles of 0.5 microns in diameter or larger per cubic foot of air, although the current limits are quoted per cubic metre. No reference is made to 5 micron particles. FDA and USP have proposed additional microbiological standards for these environmental classes. Both particulate and microbiological expectations refer to the room in the operational state only. No guidance is provided for the room at rest.

A Class 100 environment is normally expected to be a unidirectional air flow area.

EU and US Standards Compared

From the foregoing, it can be seen that the core EU and US environmental classifications are approximately equivalent to each other as shown below (N.B. using in-operation conditions):

EU Environmental Grade	Equivalent US/ISO Classification
A	100 (ISO 5)
No equivalent	1,000 (ISO 6)
B	10,000 (ISO 7)
C	100,000 (ISO 8)
D	No equivalent

Looking at these in more detail we can see that philosophy and limits/guidance values are generally very similar (see Table 1, below left).

There are some differences, however, these can be summarised as follows…

- EU requires monitoring of 5 micron particles
- EU puts more emphasis on the use of settle plates
- US puts more emphasis on personnel/garment monitoring
- EU has slightly more stringent limits for surface and glove samples in Grade A/Class 100 areas and Grade B/Class 10,000 areas.

The greatest differences are in the activities allowed in the various environmental grades.

For Terminally Sterilised Products

GRADE/CLASS	US EXPECTATIONS	EU EXPECTATIONS
A/100	Filling of products when unusually at risk	Filling of products when unusually at risk
C/100,000	Normal standard for filling of products. Product and component preparation	Normal standard for filling of products. Preparation of products when unusually at risk
D		Normal grade for preparation of product and for components

Products would be considered to be unusually at risk if, for example, the container neck is very wide and the filling speed is slow or if extensive operator manipulation is required.

For Aseptically Prepared Products

GRADE/CLASS	US EXPECTATIONS	EU EXPECTATIONS
A/100	Filling of products and aseptic operations. Optional for background filling room	Filling of products and aseptic operations
1,000	Optional for background filling room	
B/10,000	Background filling room	Background filling room
C/100,000	Product and component preparation	Preparation of solutions to be filtered
D		Handling of components after washing

Thus, FDA may have difficulty in accepting component preparation in a Grade D environment rather than Class 100,000 (Grade C).

There is, happily, good agreement between US and EU on expectations for HEPA filter specifications, air velocities at the HEPA filter face (0.45 m/sec ± 20%) and air pressure differentials between zones of different classification (10-15 Pascals).

DBA People

In each Journal we will spotlight a member of the DBA team, so that you can get to know us better. In this first issue, we focus on Jane Russell and her Romanian 'family.'

Jane Russell is a key member of the DBA office team, providing secretarial assistance to Partner, Pete Gough and all our clients and customers worldwide. When not working, however, Jane's thoughts tend to go to one particular country – Romania – and the scores of children there who have come to think of Jane as a mother.

Jane gives much of her spare time (and a large proportion of her spare cash) to the charity "Children in Distress", which provides care, support and above all love to terminally ill orphans in four hospices in Cernavoda, Pitesti, Curtea de Arges and Bucharest, Romania.

Most of the children are HIV positive and many are severely disabled. They have been abandoned by their families, rejected by society and, without the help of people like Jane, would have no life and no future.

Jane spends almost all her vacation time visiting her 'family' in Romania. They spend their days together shopping, sewing (a skill that Jane has taught to many of them) and generally just laughing and playing together. She is treated like a mother by many of the children, making it all the harder when news comes through as it inevitably does, that another child has passed away.

But it is by no means all sadness. Several of the orphans have now reached 18 years of age and more and more are becoming 'typical teenagers'. We at DBA can vouch for the joy the children bring to Jane and we are sure that she and her husband Pete bring joy in equal amounts to her extended family in Romania.

If you would like to learn more about Children in Distress, email ECliff@childrenindistress.org.uk

Here's what you think about us...

With 2006 being our 20th anniversary year we thought it was time we took stock of our training courses and the service we offer and rather than simply review it ourselves we decided we should ask our customers for their opinion.

So in March this year we ran two research studies to gain a deeper understanding of what we do well and what we need to improve. Firstly we sent out 5,000 questionnaires and asked customers to complete and return them to us for analysis. Secondly we ran two focus groups of around a dozen customers at two separate training sessions.

The response to our research was fabulous and helped us enormously to understand our customers' likes, wants and needs. All of the feedback was carefully considered – both positive and negative.

In summary it transpires that customers think:

- David Begg Associates offer great value for money
- We have tended to over communicate our courses
- We are considered to be very professional and knowledgeable
- The course content is highly relevant and easily built into workplace practice
- Some course venues can be disappointing
- Our courses are highly educational but also fun

What you said:

"They aren't just lecturing...these people know what they're talking about"

"Really up-to-date with the content of courses"

"Very good – highly rated"

"They've been doing it for a while – and it shows"

"They mailed me about this course and I was already booked on it"

...and what we are doing as a result.

We were delighted by the results of the research but as well as the positive comments giving us a great boost, the really important thing was to listen to the criticism – and act upon it.

The main criticisms revolved around two issues which were; how we communicate with our customers and the standard of some of the training venues. Clearly something had to be done to tackle these issues to maintain our high standards and the loyalty of our customers.

A better way of communicating

From now on we will be limiting our communication with you. The Course Programme will still be sent out once a year and the Journal will be sent out every four months. Individual course brochures will be sent out only once – twelve weeks ahead of the course and this will be followed up by a single email five weeks ahead of the course. And that's all!

We hope you will agree that this is a more sensible way of getting in touch. Obviously it is vital that we have your correct email address and to help us ensure your details are up-to-date you can complete the form on the reverse of the letter which came with this Journal. This would be a great help – thanks!

A better place to learn

Following an exhaustive search through the Summer, we are delighted to announce a number of new venues where we will be hosting our 2006 courses. Primarily these have been chosen based upon their strengths in two key areas:

- Quality of accommodation and conference facilities.
- Proximity to airports, motorways and railway stations

From our extensive venue search we have found eight hotels which we believe our customers will find much more suitable. Therefore we will be running our courses in 2006 at the following superb venues:

- The Hilton Hotel, York
- The Marriott Hotel, York
- The Marriott Victoria & Albert Hotel, Manchester
- The Hilton Hotel, Cobham
- The Marriott Hotel, Manchester Airport
- The Radisson Edwardian Hotel, Heathrow
- The Clontarf Castle Hotel, Dublin
- The Maryborough House Hotel, Cork

In the next DBA Journal.

The Fast Lane the challenges facing a QP involved in contract manufacturing and packing of investigational medicinal products. **Industry News** we search for news of regulatory changes so you don't have to. **DBA People** how triathlons provide Martin Lush with a means of relaxation. **Location** the Hilton Hotel, Cobham. **Forthcoming Courses** a review of training courses for Spring and Summer 2006.

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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