



news



Chairman's Review

Conference time looms once more!

This year's focus is upon the role of the microbiologist in the wider context of Quality Assurance, but not forgetting some of the essential technical detail from a strictly microbiological perspective. We are fortunate to have an excellent panel of speakers from Industry, the Regulatory Authority and specialist Consultancies. The Conference extends a special welcome to Yolanda Shoemaker from Holland and Werner Hecker from Switzerland thus providing a distinctly European flavour to the proceedings. This year, even more time is devoted to discussion sessions, thus allowing the widest possible range of special topics to be covered.

As usual, there will be an extensive Exhibition provided by specialist suppliers and I hope PharMIG members will take every opportunity to visit the stands and speak with the technical representatives, to whom I extend a very warm welcome.

Last, but not least, the Conference will allow time (just a little!) for socialising and meeting with other members of PharMIG plus the opportunity for informal discussions with our speakers and members of the Committee.

Most of you will know that Gina Butti has left the PharMIG office and through this column, I would like to thank her for her contribution to PharMIG in the short time she spent with us. Our new secretary is Maxine Moorey who is already making her mark! Maxine comes to PharMIG with in-depth experience of organising meetings and conferences especially for the Pharmaceutical Industry.

Finally, don't forget that our AGM is an important part of the Conference and I trust that some of you will think hard about joining the Committee or Working Groups. I look forward to meeting as many as possible in Peterborough in November.



David Begg
Chairman, PharMIG

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10th-11th April A Practical Training Course on Cleaning and Disinfection

This year's PharMIG course was an in-depth insight into the fascinating world of the theoretical and practical application of cleaning and disinfection in pharmaceutical/medical culture. It has been acknowledged for many years that the corner stone to maintaining a contamination free manufacturing process is cleaning and disinfection. However we are still presented with issues and challenges relating to hygienic manufacturing. This course covered a wide range of topics and not only viewed accepted methods but also challenged conventional concepts and discussed new methods of good practice.

The course was held in the pleasant surrounds of Bath University where delegates, organisers and speakers were made very welcome by site staff. Delegates were able to experience a wide range of the facilities on offer at the University, making full use of the lecture theatres, laboratories and of course the campus catering facilities and bars.

Over the two days industry experts delivered thought provoking and up to date information via a variety of methods ranging from lectures, to laboratory practical, to discussion and group work. All speakers were very open during lectures and discussions, and through out the course speakers welcomed questions and queries. Many a time a lecture or laboratory practical became a discussion forum. Industry suppliers were also on hand during the breaks to advise on products and offer solutions to equipment problems and issues.

For some delegates the course began late on the Tuesday evening where a group of nigh on strangers met for dinner, at Wessex House one of the Universities restaurants, over the course of which many engaged in stimulating conversation. As the night drew on the atmosphere became relaxed and at the evening meal one and all retired to one of the campus bars for a nightcap, "just the one Mrs Wembley!"

The next morning all were up for a hearty breakfast after which we began the day's events.

All received a warm welcome from the organisers as we registered, collected our nametags and the course agenda.

Once sat down and ready to start Poly Hajjipers, the PharMIG company secretary, introduced Dr Rosamund Baird who was then to be our guide and host for the next two days as well as an excellent

speaker. Dr Baird welcomed all the delegates with enthusiasm and her pleasant smile and manner made one and all feel relaxed and at ease.

Our first speaker of the conference was Dr Anthony Smith, who gave a very interesting and thought provoking lecture on the theory behind disinfection. Dr Smith challenged the concepts of delegates as regards to our minds set boundaries on cleaning and disinfection. Dr Smith highlighted that cleaning needs to be done prior to disinfection and that disinfection may be ineffective should there not be a cleaning regime in place. Dr Smith also brought home some of the wider issues as regards why some reagents appear not to work in some specific circumstances, and that one should be examining factors such as reagent storage time, temperature of application and dilution factors, to establish best practice. We also learnt about growing types of resistance currently being seen such as phenotypic resistance, paying particular attention to the challenges of the bio film phenotype and also considering the challenges of resistance by efflux, Mar (Multiple antibiotic resistance) and acquired resistance.

Mr Brain Metcalf, Chairman of the UK Pharmaceutical Isolator group, was next to take the floor. Mr Metcalf gave a detailed overview of the workings of isolators and key design features. Key elements such as the filtration methods, operating pressures and gassing cycles were concentrated upon. Mr Metcalf also discussed issues surrounding validation, covering all aspects needed to ensure a fully operational, validated isolator. Also highlighted was the fact that regulatory bodies are becoming ever tougher and that one must be prepared to "defend procedures and processes" as we aim for zero risk.

After a very enlightening and interesting morning of lecture and discussion all went to Wessex House for a well-earned lunch, over which delegates with specific questions collared the experts!

No rest for the wicked and after our break for lunch we were back on the quest for enlightenment.

Mrs Rachel Blount gave a comprehensive and thorough explanation of the detergents/reagents currently available on the market and the approaches as to selection. We examined the factors, which need to be considered when facing cleaning and disinfecting issues such as the temperature, contact time and substrate



compatibility. We focused closely on the application of reagents studying methods such as fogging, mopping and the triple bucket method, a concept that was new to me. Also highly debated was the issue of rotation. It was very interesting to hear in the discussion how different companies dealt with the issue and that there is still some controversy, even between experts, as to the best practice.

Ms Kim Morwood, an expert in validation work, took the next afternoon slot. Ms Morwood gave a detailed outline of the microbiological testing of disinfectants, looking closely at the regulatory body specifications and the specific stages through which it must pass. Ms Morwood passed on detailed facts, figures and references related to the testing and validation of disinfections, which I personally have found to be a very useful guide now back at my place of work.

After refreshments and a chance to look at the displays put on by the exhibitors, it was time to make our way over to the laboratories for several practical demonstrations.

Mrs Christina Bradley, Mr Mark Phelps, Mrs Rachel Blount, Mr Stuart Rolfe and Dr Rosamund Baird covered practical aspects of a variety of tests used in determining the efficacy and validation of disinfectants. Of particular interest was the hygienic skin disinfection tests CEN 1499 and 1500 and filter integrity testing using the bubble test.

The day nigh on over it was time to retire to our rooms for a quick freshen up before our 3 course evening meal, after which many retired to the bar to continue relaxing after a hard days learning!

On the second day, Amanda Lund, who had stepped into the breach at the last minute for a colleague, began with a lecture on the disinfection challenges of water systems. Highlighted during the talk was the necessity to have good design, good house keeping and suitable monitoring, in order to control the contamination risks of water systems. Mrs Lund welcomed questions and was extremely honest and candid as regards her replies, drawing examples from her own experiences and sharing solutions.

Our host and guide Dr Rosamund Baird was next to the floor, giving an insight into the theory and practical use of microbial monitoring specifically concerned with the work environment and products. Information was given as to the methods of

monitoring to be used in specific locations, such as how to monitor airborne contamination and personnel monitoring. This lecture followed on from the practical demonstration Dr Baird had given on the previous day.

Next it was time to challenge the delegates, it was time for case studies! The case studies were used to test delegate's previous knowledge and also allow them to in theory put into practice much of the information that they had learnt over the past two days. These case studies brought out many interesting questions and again highlighted the variation of approach to some problems across the industry.

Dr Ansley Crockford discussed the importance of cleaning validation to the pharmaceutical industry. The presentation addressed issues relating to the validation of equipment cleaning procedures and identifying the many factors involved in the design, validation implementation and control of cleaning programs. Guidance was also given as to the routes that may be taken to avoid product cross contamination.

Last but by no means least was Dr Bob Johnson who headed an insightful discussion regarding audits. Dr Johnson was bombarded with questions, however he did not give direct answers but lead delegates to the answer through a process of return question and answer.

It was then time for the close and for the delegates to leave after what had been two very interesting, educational and enjoyable days.

As a new comer to the pharmaceutical business I found this course extremely informative and an excellent introduction into the industry. It was a tremendous opportunity to meet industry experts, gain a wealth of knowledge and explore varied opinions in a safe environment. I found that the course introduced me to several new ideas, which I have since been able to bring back to the company and have forwarded them on to the appropriate personnel.

Katie Death



LAL Test Method: Which Technique?

by Tim Sadle

In this fairly short article I aim to offer some sign-posts for the most appropriate LAL test technique for the different samples and situations laboratories may face. The reader must note that the advice given in this article comprises only of suggestions and that a more detailed evaluation of each situation a laboratory may have cannot be given. If in doubt, the reader should seek the specialist advice offered by LAL reagent suppliers.

Most readers will be familiar with the concept of the LAL test. LAL is an acronym for Limulus amoebocyte lysate, being that extract from the blood of different species of horseshoe crab (with *Limulus polyphemus* being the most common). This extract is formulated into a reagent and a technique which can be used to meet the (now harmonised) Bacterial Endotoxin Test (BET) monographs of the European and US Pharmacopoeias (2.6.14 and <87> respectively).

There are three primary methods for performing the LAL test, and two variants, as described in the pharmacopoeias:

- **Gel-clot** [*as end-point and semi-quantative*]
- **Photometric Method: Turbidmetric** [*as kinetic or end-point*]
- **Photometric Method: Chromogenic** [*as kinetic or end-point*]

The methods share in common the fact that they work on the principle: they all use a lysate and that the lysate detects endotoxin produced from the lysis of Gram negative bacteria. This detection is based on the natural biochemical clotting mechanism which occurs within the horseshoe crab as part of its natural defence against micro-organism infection. All LAL tests modify, to

different degrees, the clotting mechanism. All of the tests require the use of an endotoxin standard (traceable to an international reference standard of *E.coli*).

One difficulty facing a modern, busy laboratory can be which test to employ for which situation? This article offers some pointers to this by briefly examining some of the advantages and disadvantages of each primary method.

Gel-clot

The gel-clot test is the most simple of the methods and the most 'pure' in relation to the clotting cascade. The technique uses different lysates which have been purified to be of a certain sensitivity (the most sensitive available being 0.03 Endotoxin Units). The test uses a low level of equipment, either a water bath or preferably a hot block operating at 37 \pm 1°C; soda lime glass tubes of 10 x 75mm and a pipette. In simple terms, an equal volume of sample is added to an equal volume of lysate and incubated for 60 minutes (\pm 2 minutes). Following this, the tube is removed and inverted through 180° in order to see if it has formed a gel ('clot') or not.

The test is made more sophisticated through the addition of positive and negative controls and a dilution series to allow an estimation of endotoxin content.

Being a relatively straightforward technique, the gel-clot test has a number of advantages:

- *It is easy to perform once trained*
- *As a qualitative test (pass / fail) it is quick and simple for product release*
- *It is relatively inexpensive (compared to its more sophisticated variants)*

- Works well for simple substances and is ideal for water testing
- Low equipment costs

However, the test had some disadvantages, not least in the increasingly regulated world:

- Semi-quantitation is possible but relatively difficult (lots of dilutions are required, which makes the test more labour intensive)
- The fixed incubation time gives the analyst no idea whether a sample will pass or fail (or even if the test will be invalid) until the incubation time is up
- Anything other than simple products or water cause test interference throughout the clotting cascade. The test is particularly prone to inhibition (as is often seen in positive product controls) due to factors like pH
- The test is limited by its maximum 0.03 sensitivity, which is a disadvantage when testing products with low Endotoxin Limits but also containing interfering factors, where necessary large dilutions reduce test sensitivity
- The method cannot be automated, which affects throughput
- The test is sensitive to vibration
- There is a degree of operator interpretation (as in 'is that a clot?') which gives it a high level of subjectivity

Turbidimetric

The turbidimetric method works in a similar way to the gel-clot. Over time, a portion of endotoxin and lysate progresses through to gelation. The turbidimetric technique measures this degree of gelation overtime by measuring turbidity via a spectrophotometer. The test employs a heated tube or plate reader, with software,

to plot turbidity (as optical density) against endotoxin concentration for a series of standards. When a unknown sample is run alongside the standards, the time taken for the unknown sample to become turbid can be measured against the onset times for the standards and the endotoxin concentration extrapolated from the curve.

There are two variants: the more widely used kinetic method, or the more labour intensive endpoint method.

The turbidimetric technique has a number of advantages:

- It is semi-automated
- It has real time measurement so that samples which are likely to fail or invalid tests can be seen relatively early (allowing repeats or out-of-specification investigations to begin early!)
- It uses software which can aid the analyst, such as, maximum valid dilution calculations; allowing sample trending and so on.
- Once validated, it can be less expensive than the gel-clot because one dilution is tested rather than a multiple tube dilution series
- Objective: the machine 'reads' the test
- Has similarities with other laboratory assays, such as, use of a plate reader, which may make it more familiar to analysts

However, there are also some disadvantages:

- Samples which are naturally turbid or have a degree of precipitation are difficult to test without large dilutions (and here MVD restrictions come into play)
- Some biologicals are difficult to test

LAL Test Method: Which Technique?

by Tim Sadle

- The initial equipment outlay is expensive
- The test is susceptible to vibration, bubbles forming in plates and tubes, and to background 'noise'

Chromogenic

The chromogenic test artificially alters what is happening naturally in the horseshoe crab to the greatest degree. The test introduces a synthetic chromogenic substrate (a short chain peptide called par-nitroaniline or pNA) into the clotting cascade. pNA is colourless but becomes yellow when dia-associated (as in the presence of endotoxin). The intensity of the yellow colour is linearly related to the endotoxin concentration. The yellow coloration is measured on a spectrophotometer, and the test is similar to the turbidimetric in its use of a standard curve to measure the endotoxin content in unknown samples.

Like the turbidimetric test the chromogenic is found as a kinetic and an endpoint type.

Many of the advantages of this technique are similar to the turbidimetric. In addition:

- It is arguably the fastest of the methods

(with tests typically taking 20 minutes)

- Turbid products and biologicals can be more readily tested

The disadvantages of the method include:

- It arguably requires the greatest amount of technical knowledge
- Samples with a degree of coloration (especially yellow) are difficult to test
- It is arguably the most expensive method in terms of reagents
- It is possibly more prone to technician variability

Summary

This article has briefly examined the different LAL tests available on the market which currently meet the BET monograph. The final choice of which method to use will come down to a number of factors including throughput of the laboratory; personal preference; type of samples being tested; complicated paperwork systems (gel-clot) offset against the horrors of software validation (photometric tests) and so on.

The summary table, based very much on my personal interpretation, below draws together some of what I have discussed:

Method	Gel-clot	Kinetic Turbidimetric	Kinetic Chromogenic
Typical detection limit	0.03 EU / mL	0.001 Eu / mL	0.005 EU / mL
Upper range	Fixed	10 EU / mL	50 EU / mL
Technician involvement	High	Medium	Medium
Ease of use	Low	Medium	High
Test robustness	Medium	Medium	High
Equipment cost	Low	High	Medium
Reagent cost	Medium	Medium	High

Conclusion

In this article it has not been possible to go into very much depth and by reading this there may not have been many answers but hopefully there have been more questions for the reader to consider! For further information I would suggest exploring the references below or discussing the subject with the various reagent suppliers.

References

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Tim Sandle is the Company Microbiologist at Bio Products Laboratory, Elstree



Editors Note

Dear reader as time goes by the newsletter gets better and less of a burden to put together because its supported by microbiologists writing articles and the committee keeping you informed of events. So most of the worries I am pleased to say about obtaining articles are over. Now what I should write is all I am left with to worry about.

With the last few issues of PharMIG News I have made some comments on practices that have more to do with compliance rather than science. I shall continue in this vein by talking about testing regimes. But before I start I would like to make the following disclaimer. As you can determine from these editors notes they are not pieces that I have pondered over for any length of time but are off the wall thoughts that I type into my PC as I spend few minutes putting them down. So take what I say with a pinch of salt but I hope that it may cause some pause for thought. Lets look at WFI systems. The FDA recommends that after the initial process qualification that each point of use should be tested for bioburden at least once a week and one point should be tested every day. This is fine for collecting data but after your system has been in operation for a few years without any counts or only a few skin organisms from sample contamination shouldn't we reduce the frequency of monitoring. But do we. I have seen trend graphs for WFI systems where there are only zero's. What's the point. There is the argument that if you reduce testing and there is a problem you could jeopardise the quality and release of more product. Then again USP 24 does state that the guidance limit of 10cfu/ml should not be used as pass fail criteria but should be used to highlight problems. How often do we reject material because of problems with WFI. Should we not reduce testing and trust in our WFI systems. Isn't this what Quality Assurance is about rather than the QC of testing quality into the system!

Paul Lovegrove-Saville
Glaxo Simth Kline

Microbiological Monitoring & Controls for Non-sterile Manufacturing

The Pharmaceutical Microbiology Interest Group (PharMIG) and the UK's Pharmaceutical Quality Group (PQG) will be holding a joint meeting on the subject of **"Microbiological Monitoring & Controls for Non-sterile Manufacturing"**.

The meeting will take place on **Tuesday 28 January, 2003** in the main hall of the **Royal Pharmaceutical Society, 1 Lambeth High Street, London.**

DEAR PharMIG

After more than two years as PharMIG webmaster I have decided to passover this responsibility to someone else.

I have greatly enjoyed being webmaster for PharMIG. The conferences have been fun and interesting and I have met some great people. I have learnt plenty and hopefully given you a useful resource.

The PharMIG website has been quite busy and it is good to see the forum on the site being used more and more. Please try and visit it at (<http://www.pharmig.org.uk/newforum/forum.php>). The more you use it the more useful it becomes.

However, as other responsibilities have crept into my life I have been finding it difficult to apply the time I feel is necessary to maintain the site properly. I have therefore handed this responsibility to a very capable person in Adam Armstrong who may now be contacted as webmaster@pharmig.org.uk.

I will of course still be available to give advice to the committee and Adam.

Lastly, I must extend my thanks to the PharMIG committee for their warm welcome and advice. Special thanks Poly, Mary-Anne, David and of course Paul.

Martin Sarosi

PharMIG Action Group

Wow, what a busy and hectic quarter we have had. Within this quarter I have changed jobs, transferred to a new site at Beckenham and recently returned from a much-needed holiday.

During this last quarter I am very pleased to say that the action groups have been very active.

• Disinfectant Group

I was able to attend the Disinfectant Action Group meeting which was held in September and am impressed at how their monograph is progressing. They have been dedicated determined in setting aggressive timelines for getting their sections completed. They will hopefully have a completed document, which will be launched at the PharMIG Annual Conference. I would like to thank Trudy and each member for there hard work. Also take this opportunity to express thanks to Roshan Bewick, who has worked hard for the group but, who has now left to start a family.

• Non-Sterile Group

Have prepared and issued their first questionnaire they have had an excellent 27 responses so far. Their next meeting is scheduled for October to collate the data. If you have not yet filled in the questionnaire or sent it off be sure to return it.

• LAL Group

Lynne met with the Parenteral Society to discuss the production of a joint monograph. This has now been agreed and they have scheduled meetings to plan an implement the new updated monograph. So we can look forward to lots of action with this amalgamated group.

• Steam Sterilisation Group

Monograph is in progress, however it's not likely to be ready in time for the conference. Hester Pearson who has been a key member of the group has resigned due to a change in Role. I would like to thank her very much for her contribution over the last 2 years.

As you can see action groups are dynamic and members leave as their roles' change. If you would like to take part in any of the action groups please contact myself on ago@pharmig.org.uk or visit the webpage on www.pharmig.org.uk .

Natasha Gibbs Action Group Coordinator

Hi I'M Maxine

I thought I would take this opportunity to introduce myself before meeting you all at the PharMIG 2002 conference in November.

I have joined PharMIG to help out with all office administration and to advise on making PharMIG even bigger and better.

I have come from a commercial conference company that was based in the City. There I headed up the pharmaceutical sector, which provided a wide variety of services to the pharmaceutical industry as a whole. These included conferences, training seminars, marketing reports and exhibitions.

We produced both local (i.e. UK only), European (including Central & Eastern Europe) and a handful of US conferences.

My aim is to use the skills and experiences I have gained to there utmost in pushing PharMIG ahead into 2003. This includes providing an even better service to you, the members, expanding into Europe and researching the possibilities of putting on an increasing amount of conferences and meetings that meet your needs precisely in the ever changing regulated world on pharmaceuticals!

If you have any ideas, suggestions or queries please do not hesitate to contact me direct via the details outlined below.

Speaking of which...we have moved! Our new offices are at:

72b The Maltings
Roydon Road
Stanstead Abbotts
Hertfordshire
SG12 8HG

Tel: 01920 871 999
Fax: 01920 871 156
Email: info@Pharmig.co.uk

Once again, I am looking forward to meeting you in November. Who knows, I may even recognise a few faces from conferences I have put together in the past!

See you there.

Max

P.S. For those of you that know Poly Hajjipieris, she gave birth to a beautiful baby girl named Eleanor. Hopefully we will be seeing Poly at the conference too.

PHARMIG WINS OXOID AWARD FOR TRAINING AT PCT CONFERENCE

Press Release 4 October 2002

The Pharmaceutical Microbiology Interest Group (PharMIG) received recognition from the Pharmaceutical, Cosmetics and Toiletries (PCT) industry at the recent PCT 2002 conference when they received a special award for training sponsored by global microbiology company, Oxoid Limited.

Brian Alexander, of Tepnel Scientific Services and PharMIG committee member, received the award on behalf of PharMIG from Oxoid's industrial product manager, Elaine Fraser (see picture).

PharMIG was formed in 1991 to provide a common voice for microbiologists within the PCT industry, particularly when dealing with regulatory bodies. Meeting every 2-3 months to discuss current regulatory and microbiological issues, members of the group share and exchange knowledge and views from their own experiences.

The services PharMIG offer to the industry include:

- on-site training visits to microbiology laboratories within associated industries and
- organisation of external training meetings and courses on specific subjects

Topics recently covered by PharMIG include, 'Surviving a Microbiological Audit', 'Biological Indicators' (a training session

held jointly with the Industrial Pharmacists Group) and 'Practical Disinfection and Cleaning' (a training course held at the University of Bath).

Training Sessions Coordinator for PharMIG, Andy Martin, comments, "The first we knew about the award was when we were told we had been nominated by the industry. Training is an important aspect of PharMIG's objectives, enabling companies to benefit from the breadth and quality of our experience. The group is dedicated and focussed, ensuring that the training courses we provide are relevant and helpful to the industry. We're delighted that the industry has recognised our efforts in this way."

The judging panel for the PCT 2002 awards were editors of various industry publications. The panel met to review, evaluate and debate the nominations for each category before deciding the winners by secret ballot.

"We were delighted to sponsor the PCT Training Prize for the second year running" says Colin Booth, Vice President Science and Technology at Oxoid. "We are equally delighted that PharMIG were the winners and applaud their commitment to the sharing of knowledge about pharmaceutical microbiological within the industry."

For further information contact Oxoid Limited on +44 1256 841144, fax: +44 1256 329728, email: val.kane@oxoid.com or visit the Oxoid website at www.oxoid.com.

PharMIG presents conference 2002

Quality Challenges in Pharmaceutical Microbiology

Wednesday 27th & Thursday 28th November 2002

The Peterborough Moat House Hotel
Thorpe Wood, Peterborough
Cambs. PE3 6SG

ABOUT THE CONFERENCE

This year's Conference puts the spotlight on both the general and specific aspects of Microbiological Quality Assurance in the pharmaceutical industry. In addition, the Conference will have a distinctly European flavour since we are fortunate to have the contributions of very eminent speakers from Holland and Switzerland, as well as those from the UK.

With the formal lectures, round table discussions and open discussion sessions PharMIG is also responding to a number of requests from members to provide some more detailed treatment of specific technical topics. However, this is not to lose sight of "big picture" issues where Microbiologists have an increasingly valuable role to play in supporting and managing Pharmaceutical Quality Assurance.

Potentially more difficult areas such as microbiological risk assessment and microbiological failure investigation, often the focus of attention for regulatory inspectors, will also be dealt with. Such issues inevitably call for fine judgement based upon sound practical experience and intuition.

Training is one of the current regulatory "hot spots" and an MCA view will challenge microbiologist's programmes on this topic.

Action group leaders will be playing a prominent role again, especially in the round table discussions.

As on previous occasions, the Conference offers

a golden opportunity for Members to meet each other and to benefit from a wide range of topics covering microbiological QA. Of equal value is the time spent discussing common issues and concerns, exchanging ideas, networking and of course, having just a little time out enjoying the now traditional entertainment which is part of the PharMIG Conference.

TABLE-TOP EXHIBITION

As an integral part of the PharMIG Conference, there will be a tabletop exhibition at the Conference providing delegates with the opportunity to meet a wide range of suppliers and their technical representatives in a relaxed atmosphere. There are ample opportunities to view the displays, particularly in the evening of Wednesday 27th November.

THE VENUE

The Conference will be held at the Peterborough Moat House Hotel in Cambridgeshire. The hotel has excellent facilities including a modern leisure centre with swimming pool and fitness centre. Peterborough is exceptionally convenient for travel by rail (approx 1 hour from Kings Cross) and by road (A1M). A limited number of rooms have been reserved at a special rate for overnight delegates (so book early).

CONFERENCE FEES

Conference fees are detailed below and include lunches, Conference banquet, refreshments and Conference documentation. Conference fees do not include accommodation and if Bed & Breakfast is required for either 26/27th November you should book directly with the hotel at the special rate of £95.00. Cheques should be made payable to PharMIG and crossed A/C Payee only. *Fees are in sterling and are VAT exempt.*

Member Fees:	£495.00
Bed & Breakfast:	£95.00
Non Member Fees:	£645.00
Bed & Breakfast:	£95.00

(B&B to be booked directly with hotel)

NB: Fees must be paid by 1st November 2002 in order to guarantee place(s) at the Conference.

REGISTRATION PROCESS

Simply complete the attached reply card and return directly to the PharMIG Administrator with your payment or fax ahead your registration details to 01920 871156. Places are reserved on a 'first come, first served' basis so book early to avoid disappointment. All places will be held provisionally until full payment is received. Confirmation of an allocated space will be sent by post with travel directions.

CANCELLATION POLICY

Written cancellations will be accepted up to 30 days prior to the event, and all cancellations will incur a fee. No refunds are available for cancellations 15 working days before the start date and full course fees will be due for delegates who fail to attend. Substitutions may be made at any time, preferably in writing to the Administrator.

PROGRAMME WEDNESDAY 27TH NOVEMBER

Chairman	Mr David Begg* PharMIG Chairman
09:30 - 10:15	Tea/Coffee and Registration
10:15 - 10:30	Chairman's Welcome and Introduction
10:30 - 11:30	Key Note Lecture Current Challenges in Pharmaceutical Microbiological QA SPEAKER 1: Dr Werner Hecker, Novartis Pharma Stein AG, Switzerland
11:30 - 12:15	Non-Sterile Environmental Contamination Control SPEAKER 2: Mr Martin Lush, David Begg Associates

12:15 - 13:45	EXHIBITION with Finger Buffet Lunch Including Round Table Discussions
13:45 - 14:30	Risk Assessment – Microbiological Issues SPEAKER 3: Mr Stewart Green, Wyeth Pharmaceuticals (UK)
14:30 - 15:00	EXHIBITION with Tea & Coffee
15:00 - 16:00	Microbial Failure Investigations Simplified! SPEAKER 4: Mrs T Jolanda Schoemaker, Crucell, Holland BV
16:00 - 16:30	Panel Discussion and Close
16:30 - 17:30	AGM (Members only)
18:45 - 20:00	<i>Pre-dinner Reception in the EXHIBITION AREA</i>
20:00 'til Late	Conference Dinner & Dance (Smart attire required)

*Honorary Member of PharMIG

c Committe Member of PharMIG

Please note that PharMIG reserves the right to alter the programme in the event of unforeseen circumstances

PROGRAMME THURSDAY 28TH NOVEMBER

Chairman	Mr David Begg* PharMIG Chairman
09:00 - 09:15	Chairman's Remarks
09:15 - 10:00	Engineering Microbiological Improvement into Existing Operations SPEAKER 5: Mr Gordon Farquharson, Bovis Lend Lease Pharmaceuticals

- 10:00 - 11:15 Open Discussion (See overleaf)
Sessions 1, 2, & 3
running concurrently
- 11:15 - 11:45 EXHIBITION with Tea & Coffee
- 11:45 - 13:00 Open Discussion (See overleaf)
Sessions 1, 2, & 3
running concurrently
- 13:00 - 14:15 EXHIBITION & Buffet Lunch
- 14:15 - 15:00 Challenging your Microbial
Training Programme
SPEAKER 6:
Mr Paul Hargreaves, MCA
- 15:00 - 15:30 Panel Discussion Session
- 15:30 - 15:45 Summary and Close of
Conference
- 15:45 - 16:00 Tea/Coffee and Departure

*Honorary Member of PharMIG

c Committee Member of PharMIG

Please note that PharMIG reserves the right to alter the programme in the event of unforeseen circumstances

Your Feedback Required

Although I am very pleased with the newsletter I wish that a few readers would drop me a line on what they think. When I say a line I would be happy with one sentence or even a few words. For example; newsletter great read it all! Editors note tosh! Or I 'm a microbiologists who's never seen the production area, help! Whatever. Contact me at the E-Mail address give below.

Paul Lovegrove-Saville E-Mail: news@pharmig.org.uk

ROUND TABLE SESSIONS - WEDNESDAY 27TH NOVEMBER

A set of round tables will be available during lunch for informal discussions on the following topics:

Disinfectant Issues

FACILITATORS : Mrs Kim Moorwood / Mrs Rachel Blount

Rapid Methods

FACILITATORS: Dr Bob Johnson c / Mr Chris Randell c

Steam Sterilisation Issues

FACILITATORS: Ms. Natasha Gibbs A c / Andy Martin c

There is no booking system; just grab some lunch, sit down and chat through any concerns/issues you may have on the specific topic - a problem shared is a problem halved!

OPEN DISCUSSION SESSIONS - THURSDAY 28TH NOVEMBER

- Session 1 Current Practices in
Pyrogen Testing
FACILITATOR : Mr Tim Sandle
- Session 2 Validation Issues –
are there any?!
FACILITATOR : Mr Neil Rose*
- Session 3 Microbial Quality in Non-sterile
Manufacturing
FACILITATOR : Mr Martin Lush

N.B. Please choose 2 of the 3 Open Discussion Sessions on your reply card