



Issue 14 Dec 03 / Jan 04

PharMIG news



Chairpersons Review

It seems impossible to me that I am sitting here writing the chairperson's review for the December / January edition of the PharMIG newsletter – where has the last year gone?

2003 was a very successful year for PharMIG – Membership continued to increase and it is something that we will continue to focus on going forward, more Members means more opportunity for all of us as it is the Members that provide the ideas and network contacts. More events, ten in total, have taken place in 2003 covering a wide range of topics. The annual conference held recently continues to be the highlight of the PharMIG calendar with a lot of positive feedback from delegates and exhibitors alike.

Much of the success of 2003 has to be credited to Maxine Moorey who was employed by PharMIG early in 2003 with responsibility for business development, including event management. Her enthusiasm and focus has ensured that the Committee met the commitments and needs of the PharMIG Members. Polly returned from maternity leave and provides Max and PharMIG with valuable support and focus, particularly as Company Secretary.

During 2003 a number of the PharMIG Committee Members changed the “day-job” – either changing company or expanding their role with their current company. Time is a precious resource, and often it seems there are not enough hours in the day, with this in mind I cannot thank the PharMIG Committee Members enough for their commitment. The Committee election at the AGM resulted in a number of role changes and new additions. You can see details of the Committee in this newsletter and on the website – if you have any questions, comments, ideas or even concerns then let us know.

2004 promises to be equally exciting and challenging. The PharMIG calendar will see its first event in Ireland and there is great excitement about the “Engineering for Non-Engineers” course scheduled for February – we think that it's the first of its kind and already generating a lot of interest. See inside the dates for the 2004 events – and mark your diary!

It remains for me to wish you all a Prosperous New Year.

Sharon Johnson
PharMIG Chair

in news issue 14...

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Editors Note



Paul Lovegrove-Saville
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Dear reader Happy New Year, I hope you had a good one. Well another year has gone and I must say it's gone very well for PharMIG. There have been more courses, meetings and visits than ever before and the annual conference was well attended, entertaining and informative. During the conference I particularly liked the way Paul Newby

energised us all with a spot of Tai Chi before speaking in the last session of the conference.

I am personally very happy with the PharMIG News and believe that it's well received. A big thanks to everyone that contributed over the last year, Poly and Maxine for doing their bit and Tim Sandle for his regular contribution and everyone that has written articles.

The web page looks good and is actively being used and updated (<http://pharmig.org.uk>). Questions are being asked and answered on the Forum page. PharMIG News is available on the web page, if you need your password to access it contact the PharMIG office (Tel: +44 (0) 1920 871 999). Passwords will be sent out when memberships are renewed in the new year.

See you in 2004

Office Update

Membership 2004

Where has the time gone? I can't believe I have been with PharMIG for over a year now and the time has come yet again for me to start sending out notice of Membership renewals for 2004!

I do hope that you all feel that you have benefited from being a Member of PharMIG in 2003 – finding the Newsletters, Conferences, Meetings, Training Courses and Site Visits both informative and of value to your everyday working life in the Microbiology arena.

With this in mind I assume you will once again want to take up Membership in 2004 and will continue to support PharMIG in its ventures for another year.

I'll be shortly sending out a form outlining the current named Members from your company and/or site. Please can you check it and update where necessary. I will also enclose a stamped addressed envelope for you to send back the revisions, plus an invoice for £350 to pass on to your accounts department.

Once I have received payments and the form back – I'll then email the main contact the new password and company ID that allows access onto the PharMIG Members website.

Which leads me nicely onto....

PharMIG Website 2004

I'm setting up an 'Advertising' page for companies to place their name and links to their site which both Members and Non-Members will be able to access.

I am also setting up a 'Recruitment' page for recruitment companies as well as pharmaceutical and Allied / Commercial companies to advertise any vacancies they have within the micro arena.

Through research there is no specific magazine or site that deals with recruitment and job vacancies specifically for Pharmaceutical Microbiologists. Consequently PharMIG have decided to take this on board and offer this unique opportunity for both employers and employees to further their business or careers. I'll keep you posted on the progress as I'll also need to call upon your help in the near future in providing me contact names within your HR and Personnel Departments so that I can let them know they can use the site to recruit new employees etc. Watch this space!

2004 Programme Schedule

We've put together an ambitious programme for 2004 (see back page – Diary Dates) which I'm confident we can achieve. It is vital for PharMIG to keep providing you with up-to-date information and to take on board new topic areas that you want to have covered, hence the increase in the number of meetings held.

We are also planning for PharMIG to expand – with our first meeting scheduled to be held in Ireland in March on Method Validation.

If you have any contacts in Ireland whom you think would benefit from a meeting on Method Validation – please do not hesitate to send me the details and I will post out a programme straight away. We need you, our Members, to help spread the PharMIG word so any advice, guidance and additional names you can pass through will be of immense help in getting PharMIG the professional recognition it and you deserve.

Right, I must get back to work or none of the items I have mentioned above will get done!

All that remains to be said is – I hope you had a fantastic Christmas and New Year and I look forward to speaking with and seeing you in 2004.

Maxie

Date for your diary

ENGINEERING PRINCIPLES FOR NON MICROBIOLOGISTS

Wednesday 11th & Thursday 12th February 2004. Kent's Hill Conference Centre, Milton Keynes.

PROGRAMME Wednesday 11th February 2004 - Chairman Mr. Gordon Farquharson - Bovis Lend Lease

09:30 - 10:00	Tea/Coffee and Registration	11:45 - 12:00	Break & allocation to Syndicate Sessions
10:00 - 10:15	Chairman's Welcome and Introduction	12:00 - 13:00	Workshop Sessions - 1, 3, 4 & 5
10:15 - 11:00	Critical Utilities - Peter Wilkinson <ul style="list-style-type: none"> ● What are They and Why are they important ● Design & Specification ● Installation & Commissioning ● Validation & Start up ● Routine Operations 	13:00 - 14:00	EXHIBITION with Finger Buffet Lunch
		14:00 - 15:00	Workshop Sessions - 1, 2, 4 & 5
		15:00 - 15:30	EXHIBITION with Tea/Coffee
11:00 - 11.45	Hygienic System Design - Chris Davis <ul style="list-style-type: none"> ● Review of Design Guidelines ● Selection of Materials ● Process Design for Sanitisation ● Design Tools 	15:30 - 16:30	Workshop Sessions - 1, 2, 3 & 5
		16:30 - 17:30	Workshop Sessions - 2, 3 & 4
		18:30 - 19:30	Pre-dinner Drinks and Exhibition - Followed by dinner

PROGRAMME Thursday 12th February 2004 - Chairman Mr. Gordon Farquharson - Bovis Lend Lease

08:30 - 09:15	HVAV Systems & Environmental Control <ul style="list-style-type: none"> ● Understanding the New Annex 1 and its Implications ● HEPA Filter Selection & Testing ● System Engineering to Control Critical Parameters ● Performance & Critical Parameter Monitoring 	10:00-10:30	EXHIBITION with Tea/Coffee
		10:30-11:30	Workshop Sessions - 6, 8, 9 & 10
		11:30-12:30	Workshop Sessions - 6, 7, 9 & 10
		12:30-13:30	EXHIBITION & Lunch
09:15-10:00	Sterilisation Issues - Keith Shuttleworth <ul style="list-style-type: none"> ● Common Regulatory Issues ● Steam in Place ● Physical v Biological Approach to Validation 	13:30-14:30	Workshop Sessions - 6, 7, 8 & 10
		14:30-15:30	Workshop Sessions - 7, 8 & 9
		15:30-16:00	Discussion & Close

THE WORKSHOPS AND IMPORTANT INFORMATION

Workshop 1	Water Systems - Lee Eyres, Christ Kennicott Water Systems
Workshop 2	Compressed Air/Gases - Karin Weikel, Millipore
Workshop 3	CIP - Chris Davis, BLLP
Workshop 4	Hygienic Process Systems - Peter Wilkinson BLLP
Workshop 5	Managing Engineering Intervention - Julian Calvert, Baxters HC
Workshop 6	HVAC - Non-sterile manuf - Tony Melling, MSS Clean Technology
Workshop 7	HVAC for Cleanrooms - Gordon Farquharson, BLLP
Workshop 8	Clean Room Technology - Thair Hussain, MRC Systems Ltd
Workshop 9	Moist Heat Processes - Keith Shuttleworth, KS & Associates
Workshop 10	Dry Heat Processes - Peter Wilkinson, BLLP
<p>Please note that the Workshop sessions will run concurrently at the allocated times. Delegates must nominate one session on each day that they DO NOT wish to attend on their reply cards i.e. each delegate will be able to attend 4 out of the 5 workshops each day.</p> <p>CONTACT: Maxine on 0920 871 999 or email: Maxine@pharmig.org.uk for more information or to reserve a place.</p>	

PharMIG Annual Conference 2003

The Diverse Pharmaceutical Microbiologist

By: Maura O'Toole – GlaxoSmithkline, Beckenham

This year, once again, a large number of microbiologists gathered together at the Stratford Manor Hotel, Stratford-upon-Avon on the 18th and 19th of November for the annual PharMIG conference on the theme of The Diverse Pharmaceutical Microbiologist. I had missed the conference for the past few years and as the crowd assembled, I was delighted to see again the familiar faces of those that I met at previous conferences as well as many new faces. The annual conference seems to go from strength to strength and attracts delegates from many of the pharmaceutical companies operating in the UK as well as a diverse range of speakers with a wealth of experience in the industry and with the regulatory authorities.

After a welcoming cup of coffee and registration, the delegates gathered in the hall and the conference was opened with a short introduction by Brian Alexander who chaired the sessions on the first day. The first presenter of the day was Richard Andrews, a GMP inspector with the MHRA. He gave us an insight into the structure of the MHRA itself and the different types of regulatory inspection that they carry out and how they impact on microbiology. Richard also gave an interesting insight into recent inspection findings and identified the types of critical/major deficiencies that inspectors have found during these GMP inspections. The message that I took away from this session was that the microbiologist must play a proactive role at all stages of the process, from plant design to product release, to ensure it remains under control. Inspectors expect timely investigations into the root cause of product failure so that steps can be taken to eliminate the risks to product.



Kay O'Hagan, from Bovis Lend Lease, spoke about the microbiological aspects of manufacturing control of APIs and the microbial risks associated with different types of

manufacturing process and the factors that impact on the level of that risk. She gave us information on how to assess the risk associated with the different sources of contamination - from raw materials to packaging- and how individual steps in the production process can either promote or inhibit the growth of microbial contaminants. Kay stressed the importance of having a valid sampling regime in place because any microbial contamination may not be uniform throughout a batch.



A buffet lunch was served in the bar/exhibition area and this gave everyone a chance to mingle and meet other delegates as well as fitting in a visit to the many exhibitors' stands. This year, there were a large number of exhibitors present and this was a great opportunity to chat to suppliers and find out about new developments in equipment and test methods and to collect information and also some free gifts (for those who got in early).

After lunch, Marie Rabouhans gave an informative talk on regulatory issues for non-monographed raw materials from a microbiological perspective. As well as explaining the role of a pharmacopoeial monograph in setting an accepted standard and specification, she also dealt with the problems encountered where one wishes to use a raw material where no monograph exists. She gave many pointers on how to define the required quality of the raw material based on the intended use, the importance of specifications and the roles that supplier audits and testing play in ensuring that materials consistently meet these standards.

Paul Lovegrove-Saville introduced us to some of the quality issues that are encountered with contamination control in the biopharmaceutical industry. The processes used in biopharmaceutical production are



more susceptible to contamination with a range of micro-organisms because many steps in the production of an API can support, or indeed, promote the growth of these contaminants. Paul described a generic Biopharm process from the stage when a master cell bank is laid down until the final product is formulated and stressed the special problems encountered when the raw materials used may be from human or animal origin - i.e. contamination with TSEs, viruses, bacteria, moulds or mycoplasmas. It is important that both the master and working cell banks are free from adventitious agents and that the appropriate environmental controls are in place during production to ensure that the product is not compromised. This is especially important as some stages of the process involve sanitary rather than aseptic processing and he suggested a testing regime that would meet this requirement.

In the next presentation, Dr Trevor Deeks from Fluor Ltd. reminded us what a "process" means in the eyes of the regulatory authorities and emphasised the importance of recording all process deviations and out of specification

test results. Each deviation should be approved in writing by a competent person and with the involvement of the Q.C. Dept. and there should be a timely investigation into the reason for any process deviation followed by a product impact assessment. He discussed some of the essential steps in carrying out an investigation and this was illustrated with examples from three different case studies and he stressed that where the cause of the deviation was clearly identified, there should be a plan for remedial action to prevent a recurrence.

As the main theme of all the sessions seemed to be about knowing and understanding the production process and assessing/minimising the associated risks, it was appropriate that the final presentation of the first day was about a systematic approach to assessing risk. Tim Eaton from AstraZeneca introduced us to a modified HACCP approach to formally identifying and assessing the areas of greatest microbiological risk. During his talk, he explained how to identify risk factors, how to evaluate each factor by assigning an individual score, how the effectiveness of the control measures in place can modify risk and how to achieve a final risk rating for any particular process or part of a process. This was an interesting and, one could say,



scientific approach to risk analysis. The first day ended with all the presenters on the rostrum taking questions from the floor and some lively discussion followed before everyone dispersing to prepare for the evening's festivities.

We all gathered together again after 7pm for a welcome pre-prandial drink before enjoying the conference dinner. After a lovely meal, the band began to play and it was not long before the more energetic of us took to the floor. As the evening progressed, the floor became more packed and it appeared that a good time was being had by all!



On the Wednesday morning, the delegates (most of them) gathered in the conference hall for the first session. Mike Breese gave us a comprehensive lecture on the different types of water used in biopharm production and the regulatory requirements for each type of water. He also spoke of the problems caused by contamination of water systems and how to set up controls to monitor this.

The rest of the morning was given to open discussion groups on different topics where delegates chose two out of the four groups to attend. I attended the session on Water Activity where Richard Benton gave a short talk explaining what it was and how it was applied in AstraZeneca to predict and determine the shelf life of dry products. I also attended the Process Validation talk and found, that at each session, there was lively discussion and those present were happy to share their experiences and discuss problems they had encountered.

Delegates gathered for a hearty lunch and had the opportunity to sit around for a while to chat, making new friends or catching up on news with friends from previous conferences.

The afternoon session started with a comprehensive talk by Barry Cook and Andy Clark on the regulations governing the use of electronic records and signatures in the laboratory. At the end of the talk, I felt that I had a clearer picture of what exactly was covered in the revised version of the infamous 21CFR Part 11 and what was necessary to do to achieve compliance.

Paul Newby was the final presenter of the afternoon and before beginning his introduction to PAT (Process analytical technology), he ensured that all the delegates in the hall were awake and alert by having them perform some Tai-chi exercises. When we were all seated again, with minds alert and warm ears, he gave a very interesting talk on the role of PAT in assuring the quality of product through the analysis of real-time or near real-time data. He discussed the advantages of using of rapid microbiological methods as part of PAT and spoke about some of the new technologies that were available for use to speed up microbiological analysis of samples i.e. ATP bioluminescence and the Chemscan. He also acknowledged the cultural and technological barriers that need to be overcome before the pharmaceutical micro lab entered the 21st century.

The conference drew to a close with a final panel discussion covering the topics of the day and a short closing speech from the Chairman. After some quick refreshment, the delegates began to depart for home and the PharMIG conference was over for another year. It was a very informative and enjoyable occasion and everything went without a hitch thanks to the excellent work and organisation of all the participants.



PharMIG



Annual Conference



How to Implement, Validate and Register Rapid Microbiological Methods

By: Paul J Newby PhD GlaxoSmithKline Research

Introduction

Outlined in the following text is an holistic approach to the implementation, validation and registration of Rapid Microbiological Methods (RMMs) for the pharmaceutical industry. Interest in the area of RMMs is high due to the appearance of a number of RMM test systems designed for use in the pharmaceutical sector. Successful registration and use of RMM test systems is however low. Uptake of these new methods is still in its infancy, which is strange when you consider similar methods have been successfully adopted by other industrial sectors for several decades. Establishing a clear implementation route will help increase the uptake of these systems and will bring with it many scientific and business benefits for the pharmaceutical industry.

Introducing new microbiological methods into the pharmaceutical sector is no easy task. Broth enrichment, pour plating, and use of selective differential agars are the mainstay of modern pharmaceutical microbiology. These conventional methods used for enumerating and identification of microorganisms in pharmaceutical products are far from modern. They have, in fact, been around since the latter part of the nineteenth century. These methods have been highly successful, cheap and simple to perform. Unfortunately they are also labour intensive, take between 5 to 14 days to produce results and require expert interpretation. In addition, they are impossible to automate and will never provide real-time data for accurate and responsive process control. In short conventional microbiological methods are:

- Potential bottlenecks to production and batch release
- Not suitable for real-time/ near real-time results

Such methods will not provide a suitable platform for future methods. Future methods will need to provide:

- rapid results
- real or near real-time data
- in-line or at-line testing
- automation and high test throughput potential
- highly labour efficient

There is a real need now for the introduction of new methods, which can address the requirements of a highly

technological industry in the twenty first century. It is no longer appropriate to use nineteenth century techniques in a modern pharmaceutical industry. The time is right for the uptake of new microbiological methods, which will provide solutions for current, and future needs.

Process Analytical Technology & RMMs

Implementation

Consider your needs:

Before investing in expensive new technology it is important to consider why you need the test system in the first place. This may seem obvious but there are many such 'technological solutions' sitting on laboratory benches all over the world doing no more than gathering dust. Some factors to consider in attempting to understand your requirements include

- what is the purpose of the current test
- do you need to test at all
- what are the real business drivers in changing to new technology
- what are your current/new test requirements

An initial evaluation of any potential new system is highly recommended. A good supplier will offer a loan or short term rental agreement for any prospective customer. Careful consideration needs to be given to this evaluation. The system must be tested for its ability to do the job. It is important that a true impression is gained at this stage. If not a costly mistake with subsequent headaches for unwary users will follow. In addition, it will be all the more difficult in future to persuade managers and financial departments to invest in other new methods.

An important tool in helping persuade management and finance departments of the merits of RMMs is an effective business case. Historically microbiology has not required high capital cost equipment unlike the more automated chemical analytical laboratory. An effective business case will help enlist the support of senior managers and company finance personnel. Good science alone is not enough in today's cash strapped industrial environment to secure purchase of a RMM test system.

Validate and Register Microbiological Methods

& Development, Ware , United Kingdom.

Some points to consider for a business plan include:

- the true cost of the current test (facilities, reagents, consumables – not just an agar plate!) versus the new system
- labour costs – plus labour savings for the RMM
- effect on batch release,
- does the current test reduce operating efficiencies – is it a bottleneck
- quality & compliance issues
- patient benefits

A User Requirement Specification (URS) is a very useful way for the user to define what is required from a new test system. The document is a good foundation for defining what the user wants and what the supplier is being asked to deliver. The URS is the foundation for effective implementation. It also acts as a key reference point for

the validation of the system.

PDA Technical Report 33 Vol 54(3) ' Evaluation, Validation & Implementation of New Microbiological Methods' is an excellent reference document for anyone interested in evaluating RMMs. It gives an overview of vendor implementation, selection, technologies and validation.

Validation

Following a successful initial evaluation and purchase the next step is validation. RMM test systems are increasingly based on complex technological platforms. It is important to focus any validation effort on both the **microbiological performance** and the **technology platform qualification**. An effective model for this is the System Qualification Model – used for compute validation and also known as the 'V' Model – see Figure 1.

System Qualification

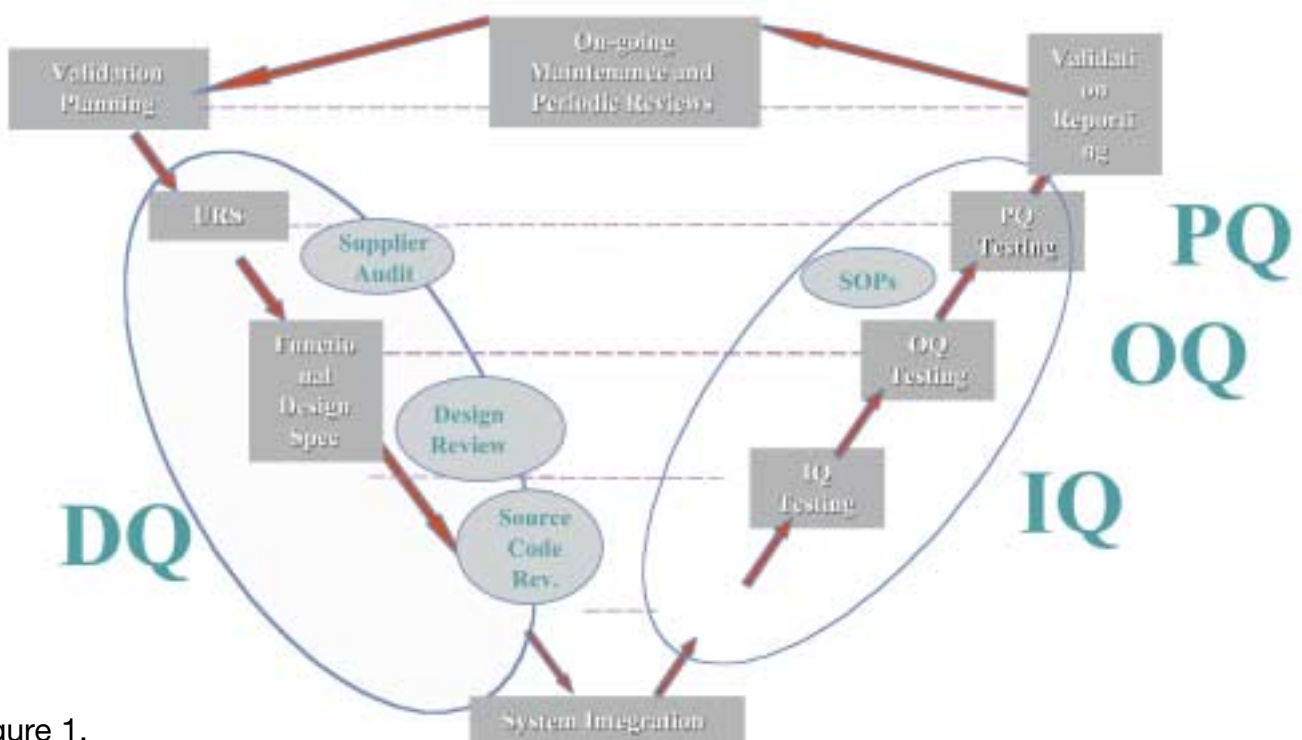


Figure 1.

Design Qualification (DQ)

A Validation Master Plan developed at the outset of the validation exercise, which outlines the approach to be taken for the RMM evaluation, is an effective first stage. This will include both equipment and microbiological performance evaluation details.

During DQ user requirements will be outlined and documented in a User Requirement Specification (URS). The document will be used as a basis for defining subsequent validation testing.

Evaluation of computer hardware and software components will be carried out during DQ if considered necessary. A supplier audit may be required due to the novel nature of the application. It may also be required because the system may be bespoke.

Installation Qualification (IQ)

The IQ stage will verify and document that the RMM has been supplied and installed as specified by the supplier.

Operational Qualification (OQ)

OQ will verify and document operating parameters of the RMM by the use of compendial organism and may include environmental organisms. Equipment qualification should be considered at this stage to ensure correct operation of the RMM under working conditions. Individual tests should be outlined in specific protocols with defined acceptance criteria.

Performance Qualification (PQ)

PQ will demonstrate fitness for purpose of the RMM. Testing will comprise of a parallel evaluation of manufactured batches with the registered test method. Testing should be outlined in specific protocols with assigned acceptance criteria. The RMM will be expected to demonstrate equivalence with the existing test method.

Registration

In Europe a new draft regulation 'European Directive 2001/83/EC' will give the legal basis for new regulations. Under these new regulations it is proposed that any novel or non-standard technique is likely to be classified as a Major type II variation. Currently such techniques are regarded as Type-I variations. Type-II variations will require

- an expert report
- formal assessment process
- formal pre-approval letter

This whole process may take 4 to 6 months.

In the United States the situation is somewhat the reverse. The FDA is actively attempting through a variety of initiatives to simplify or clarify the submission process for RMM technologies. According to the 1999 FDA guidance document 'Establishing a new regulatory analytical procedure' is a major change. Major changes require Prior Approval Supplements (PAS). However, the advent of **Comparability Protocols** will allow initial discussion for new technologies which may lead to a simplified reporting category such as a **CBE30, CBE 0 or Annual Update**.

Introduction of RMM techniques for in-process applications may be simpler. It is important that the user and regulatory authorities have an awareness of the technology/ies in question if swift implementation is to occur. So it is vital that effective dialogue is established between regulators, users and manufacturers of new test systems to permit swift and painless implementation in the future.

Conclusions

Interest in Rapid Microbiological methods in the pharmaceutical industry is high. There are significant benefits in speed of result, process efficiency saving, sensitivity and business benefits to warrant this interest. Increasingly it is realised that current techniques do not offer a viable platform for future industry requirements in terms of real time or near-real time results and throughput efficiencies.

RMM test systems designed specifically to cater for the requirements of the pharmaceutical industry have been developed in close collaboration between customers and some suppliers. RMM systems are commercially available which are suitable for use in the pharmaceutical sector.

Implementation is a complex topic, however, it is not impossible. Documents and advice are now available that will facilitate successful uptake of RMM test systems. Increasingly dialogue between suppliers potential users and regulatory authorities is clarifying and defining submission strategies. Registration and use of such systems is happening across Europe and the rest of the world.

Implementation of Rapid Microbiological Methods poses some risks but offers the potential of significant benefits. RMMs also position pharmaceutical microbiology for the future. We must have the courage of our convictions if these benefits are to be realised.

ARE YOU IN COMPLIANCE?

By: Hazel Sarosi – Sanofi-Synthelabo

Compliance
Corner

Firstly I would just like to say what a thrill it is for me to be back on the PharMIG Committee. I have missed working with fellow Members over the last two years as I have grappled with the concept of analytical chemistry and Quality Control, soon to discover I am still a microbiologist at heart!

I have volunteered to author a regular article in the newsletter to capture all those things that have been happening in the world of Pharmaceuticals that may have an impact upon YOU, the Pharmaceutical Microbiologist, or your direct environment. As you can imagine, to perform this review for the last twelve months has been quite some task and my thanks must go to Chris Thompson for meticulously reviewing the Pharmacopeial Forum and the Pharm Europa since I can remember. The following summary may not be exhaustive and, where there has been repetition within both the Pharmacopeial Forum and the Pharm Europa then they will only appear in one reference.

PharMIG's objective for 2004 is to provide a forum to give you the opportunity to comment on future updates at the consultation stages of the harmonisation process. Please do feel free to email me in the first instance on info@pharmig.org.uk with your observations, queries or comments. I look forward to hearing from you.

PHARMACOPEIAL FORUM (Vol. 29 No. 1, January – February, 2003)

First Interim Revision Announcement
General Chapters

<1196> Pharmacopeial Harmonization – new

chapter describing the ICH process and listing (page 37) of the status of harmonization (responsible pharmacopeia, stage achieved to date) of some excipient monographs and general chapters.....this is well worth reading to ensure that you fully understand the harmonisation process, especially when various harmonised text, mentioned later, are published for review at various stages of the process.

Other areas of interest in this issue include;

<1209> Sterilization – Chemical and Physicochemical Indicators and Integrators – revised 1994 version following comments received.

<1222> Terminally Sterilized Pharmaceutical Products – Parametric Release – revised 1997 version following comments received.

<1223> Validation of Alternative Microbiological Methods – proposed new chapter that previously appeared in Pharm Forum 28-1 Jan-Feb 2002.

PHARMACOPEIAL FORUM (Vol. 29 No. 3, May – June, 2003)

USP27 – NF22 is due for publication in November 2003 and becomes official January 2004.

Supplement 1 will be published in February 2004 and become official April 2004.

Supplement 2 will be published in June 2004 and become official August 2004.....useful to know to ensure that you have current compendia available for use

Other areas of interest include;

<1072> Disinfectants and Antiseptics – revised chapter first seen in PF (28) 1 Jan-Feb 2001.

<1230> Water for Health Applications – new chapter first previewed in PF (28) 5 Sept-Oct 2002 which has been amended following comments received– gives the chemical and microbiological quality of water required for haemodialysis.

<1117> Microbiological GLPs – new chapter comments by October 1st 2003.

PHARMACOPEIAL FORUM (Vol. 29 No. 4, July– August, 2003)

Fourth Interim Revision Announcement

<71> Sterility tests

Harmonized text.

<797> Pharmaceutical compounding – sterile preparations

<1196> Pharmacopeial Harmonization

Description of the process, stages and glossary of terms also includes a list of the status of various excipients and general chapters.

Having previously suggested that when a particular reference has been made in both Pharmacopoeial Forum and Pharm Europa only one would be cited, I felt that the following harmonisation initiative was worthy of a mention in both. There are slight differences in EP, USP and JP text though these are clearly noted by way of footnotes when they arise. Don't forget harmonisation does not mean unity!

PHARMEUROPA (Vol. 15.3 July 2003)

International Harmonisation

5.1.4. Microbiological Quality of Non-Sterile Pharmaceutical Products

2.6.12. Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests.

2.6.13. Microbiological Examination of Non-Sterile Products: Tests for Specified Micro-organisms.

PHARMACOPEIAL FORUM (Vol. 29 No. 5, September – October, 2003)

<61> Microbial Limit Tests

Replacement Stage 4 now titled 'Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests'.

<62> Microbiological Examination of Non Sterile Products: tests for Specified Micro-organisms.

Revised Stage 4 publication.

<1111> Microbiological Quality of Nonsterile Pharmaceutical Products

Stage 4 based on a revised Stage 3 publication.

There are a few proposals that may be adopted so we will be watching the final proposals for these revised chapters. The deadline for comment was 31 October 2003.

Other areas of interest include;

NF Monographs

Pregelatinized Starch

Update to microbial limits.

<1231> Water for Pharmaceutical Purposes

Revised chapter.

Finally please note the following major changes coming from the EU. Commission Directive 2003/94/EC, laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use replaced Commission Directive 91/356/EC as of 8 October 2003. Also there have been two Annex revisions to the 'Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2002', these are revision of Annex 01 (May 2003) –Manufacture of Sterile Medicinal Products and Annex 13 (July 2003)-Manufacture of Investigational Medicinal Products which leads us nicely to the final consultation stages which occurred earlier this year with respect to 2001/20/EC – The Clinical Trials Directive. More about that next issue....

PharMIG Action Groups

For those of you still recovering from the PharMIG conference what a fantastic quality microbiology event it was. I would like to thank those who voted me back onto the Committee as the Action Group co-ordinator for another term. I look forward to getting the disinfectant monograph issued and working with the current Action Groups to produce information that is useful to the PharMIG Members. In the next two years, I need you as members to identify areas of expertise or interest that you would like to present to the industry through initiating a new Action Group.

I would like to thank Richard Benton from AstraZeneca, the Water Activity Action Group leader, who chaired two open discussion groups at the conference. He gave an excellent presentation on the background to Water Activity, how it has been used within his company and how it could be implemented in other pharmaceutical microbiology labs as a rapid test methodology. PharMIG looks forward eagerly to see what this Action Group has to offer in 2004. If you are interested in joining, please contact me.

There have been a number of changes with the other Action Groups, due to individuals in the team's role changing. Lynne Arnot the Endotoxin Testing group leader has recently changed companies and has

stood down and I would like wish Lynn all the best in her new role and to thank Tim Sandle for taking on the role of Action Group Leader. This team has been working with the Parenteral Society on an updated Endotoxin testing monograph, which will be progressed further in 2004.

The non-sterile and steam sterilisation Action Groups continue to function.

The Disinfectant Action Groups monograph is progressing more slowly than anticipated, but this is to ensure that PharMIG produce a document of the highest standard to aid you the pharmaceutical industry. I would like to thank Trudy Adjrah and her team for all of the efforts that they have put into the preparation of this document.

The Action Groups are dynamic and do accept new Members if you would like to know more information about the Action Groups or would like to participate in one then please contact me at Natasha.sc.gibbs@gsk.com.

Finally, I hope you had a great Christmas and wish you a productive New Year.

Natasha Gibbs
Action Group Co-ordinator.

Update from AGM Meeting on 18th November 2003

Notice to all Members:

With reference to the AGM Meeting held on Tuesday 18th November 2003 - 23 delegates from 19 companies were present.

Reports were presented by: Chairperson, Treasurer (presented by Vice-Chair) and Secretary. Draft AGM minutes will be issued to all Members by the end of the first quarter of 2004.

The AGM moved on to elect the new Committee. Poly Hajipieris chaired the election process and the following people were elected onto the Committee for 2004 – 2006 inclusive:

Election of the Committee

Position	Nomination	Proposed by:	Seconded by:
Chairperson	Sharon Johnson	Rachel Blount	David Begg
Vice Chairperson	Brian Alexander	Sharon Johnson	Chris Randell
Treasurer	Andy Martin	Brian Alexander	Hazel Sarosi
Action Group Co-ordinator	Natasha Gibbs	Sharon Johnson	Rachel Blount
Editor and Comms Co-ordinator	P Lovegrove-Saville	Andy Martin Chris Randell	Brian Alexander Brian Alexander
Technical Advisor	Rachel Blount	Natasha Gibbs	Hazel Sarosi
Technical Advisor	Bob Johnson	David Begg	Sharon Johnson
Technical Advisor	Peter Knott	P Lovegrove-Saville	Poly Hajipieris
Technical Advisor	Kim Moorwood	Rachel Blount	Andy Martin
Technical Advisor	Chris Randell	Brian Alexander	Hazel Sarosi
Technical Advisor	Hazel Sarosi	P Lovegrove-Saville	Chris Randell

Following the election, the floor was open to Members:

Natasha Gibbs stated that there was a requirement for a Deputy Action Group Co-Ordinator (please contact Natasha directly if you are interested in taking on this role – Natasha.sc.gibbs@gsk.com)

Chris Randell (Wyeth) & Paul Newby (GSK) would like a Rapid Methods User Group incorporating PAT to be re-established under PharMIG.

Paul Lovegrove-Saville would like to request all Members to continue to submit articles for the newsletter or website.

A special thanks to Tim Sandle for his frequent contributions to the newsletter – keep 'em coming!

PharMIG Diary Dates - Draft Events Schedule 2004

January - June 2004

February 11th & 12th 2004

Engineering Principles for Non Engineers
2 Day Training Course

March

Practical Approaches to Microbiological Method Validation IRELAND

March 23rd

Practical Approaches to a Microbiological Audit

April

Joint meeting with PQG - TBC

Microbiological Monitoring & Controls for Non-Sterile Manufacturing

April

Site Visit

May

Biotech Meeting

June

Microbiological Data & Statistics

June

Engineering Principles for Non Engineers IRELAND

June

Cleaning & Disinfection Meeting combined with Site Visit

Note: This programme may be subject to change and companies will be notified accordingly

Note: As soon as dates are fixed for the various meetings - companies will be notified

Full details will be mailed in due course. In the meantime if you have any questions regarding the event schedule please do not hesitate to contact

Maxine Moorey on (T) 01920 871 999 (Email) Maxine@pharmig.org.uk

PharMIG Diary Dates - Draft Events Schedule 2004

July - December 2004

July

Endotoxin Meeting

September

Practical Approaches to Microbiological Method Validation

September

Surviving a Microbiological Audit

IRELAND

October

Management skills for Microbiologists

October

Site Visit

November

PharMIG Annual Conference

December

Rapid Methods

Note: This programme may be subject to change and companies will be notified accordingly

Note: As soon as dates are fixed for the various meetings - companies will be notified

Full details will be mailed in due course. In the meantime if you have any questions regarding the event schedule please do not hesitate to contact

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