



news

Chairman's Review

Another year is already underway and I would like to take this opportunity to wish you, the Members of PharMIG, your friends and families, all the very best for 2003.

Many of you will already know that David Begg stood down as Chairman of PharMIG at the 2002 AGM and I was elected to replace him, so I thought I'd use my first PharMIG Chairman's review to introduce myself a little bit to you all. I have 22 years experience in the industry with a variety of dosage forms but am particularly interested in Sterile product manufacture. I started my career as a trainee technician at the bench, doing all of those jobs that trainees do including a rapid introduction to autoclaving waste media – the memory of which has stayed with me to this day including "that smell" that is instantly recognisable in every lab! After moving to Revlon Healthcare (that became Rorer, that became Rhône-Poulenc-Rorer, that became Aventis!) for a total of 15 years, firstly at their Eastbourne facility then at the Dagenham site, I now work for Baxter Healthcare in a European role. In addition I am registered with the IOB as eligible for nomination as a QP, and have been a QP assessor for the IOB for the last 5 years.

Throughout my career I have maintained a great enthusiasm for all things related to Pharmaceutical Microbiology and want to use this enthusiasm within PharMIG. There are continuing challenges in the industry that we work in, and as is often said we should see such challenges as opportunities – to improve the things that we do and / or to re-visit the things that we do today so increasing our understanding of why practices and procedures have been adopted and continue to be relevant. It has always been a need of mine to understand "why" – even with time and resource pressures it is important that "the why" and the consequences of "if not" are included in training and coaching activity.

As a PharMIG Member you should use PharMIG as a resource to support your training programmes. If a course or topic is not currently available in the PharMIG calendar you need to make the Committee aware so that action can be taken to address the gap. Courses can only be made available if there is sufficient demand but if you have a need that does not have the demand to warrant a course use the PharMIG website and network of Members to obtain contacts who can give help.

2002 closed with a successful Conference, notwithstanding the fact that too many PharMIG Members left without all that they brought with them!. There is much planned for 2003 so mark your diary and lets continue to grow PharMIG to all that it can be.
Until the next time,

Sharon Johnson
Chairperson, PharMIG



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PharMIG Membership Subscription 2003

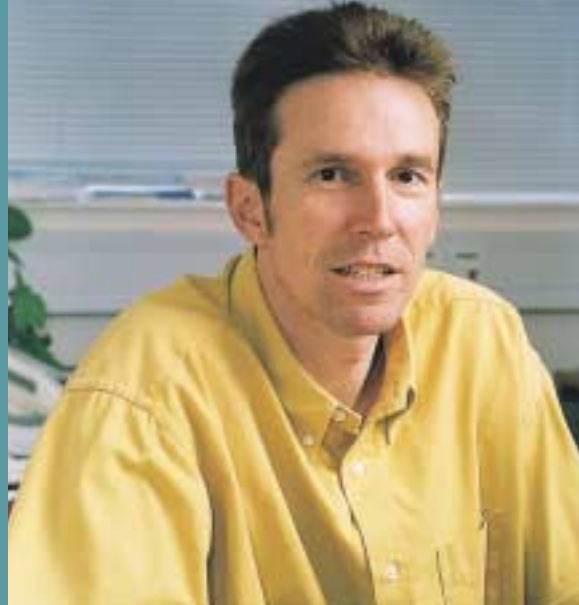
Dear All,

I hope you had a great Christmas and New Year and are now looking forward to the series of conferences, meetings, training courses and visits that PharMIG are currently finalising for 2003.

Just a quick reminder that Membership renewal is now due for 2003, the cost of which is £325 for the year. I am in the process of sending out forms and reply envelopes etc to all existing Members. I will also be targeting new companies with the aim to expand the Membership database in order for PharMIG to provide even more programmes to suit your needs and to keep you abreast of current changes and issues surrounding the Microbiology arena.

I do hope you want to continue to support PharMIG into 2003. I look forward to receiving your forms back in due course. Any questions please don't hesitate to call me on 01920 871999 or email me on info@pharmig.org.uk.

Max



Editors Note

Dear Reader

Happy New Year. I hope that you had a good Christmas and have all recovered from the festivities. If you are still recovering it was a lot heavier than my Christmas. January is often regarded as a slow quiet month that drags by but for me its passing at a rate of knots. Work is busy with plenty of new challenges but what is unusual for this time of year is my social diary is full of parties. What a great way to start the year. Life is good.

Lets reflect now on how last year was for PharMIG. It was very good but then I am going to say that being on the Committee and all. But it was really a very productive and successful year. The Action Groups lead by Natasha Gibbs have carried out a tremendous amount of work in performing surveys, collating data and publishing results and are working towards the publication of monographs. I personally feel that the PharMIG 2002 Conference was the best yet. The speakers, the content, the trade stands and the entertainment were excellent. The Cleaning and Disinfection and Surviving a Microbiological Audit courses were a success too. The newsletters, well what can I say! There is however, always room for improvement across the board. We can't rest where we are. The web page had a few problems last year but it looks like this will be imminently sorted and we can improve it and make it more active for 2003. David Begg's leadership has taken PharMIG forward and ensured its success and I am sorry to see him leave. However I am confident that Sharon Johnson will build upon the past good work and develop PharMIG so that we have a larger Membership, greater influence and will continue to meet the needs of Pharmaceutical Microbiology.

Paul Lovegrove-Saville

E-Mail: news@pharmig.org.uk

Surviving a Microbiological Audit Robinson College Executive Centre, Wyboston, Bedfordshire

Programme Thursday 24th April 2003

09:30 - 10:00	Registration with Tea/Coffee
10:00 - 10:15	Chairpersons Welcome Mr Andy Martin
10:15 - 11:15	What an Auditor would expect to find in a Microbiological Audit Miss Natasha Gibbs
11:15 - 11:30	Tea/Coffee Break
11:30 - 12:30	Interactive Session A Essential Behavioural Skills Mr Les Meader
12:30 - 13:45	Lunch
13:45 - 14:45	Interactive Session B Audit Scenarios and Discussion Mr Andy Martin
14:45 - 15:00	Tea/Coffee Break
15:00 - 15:45	Topical Issues in Pharmaceutical Microbiology Dr Robert Johnson
15:45 - 16:15	Panel Discussion with Speakers
16:15 - 16:30	Summary and Close

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

Fee: £350 Members

£400 Non Members

Contact: Maxine Mooney on 01920 871999 for more details

Surviving a Microbiological Audit

on Sept, 18th 2002

Summary of meeting written by Trudy Adjrah

This is the second year this course has been run, which on this occasion was set in the pleasant grounds of the Belton Woods Hotel, in Grantham.

24 delegates attended the course from 16 pharmaceutical and associated companies in the UK.



Andy Martin was an enthusiastic and able Chairman for the day and set about introducing the course and its aims--of the importance of auditing to our industry and that as scientists we are often involved in audits. Consequently the need to understand the required behaviour and techniques used by the auditors and inspectors.

He started off by asking people why they were there, and a variety of answers were given. Some were new to the job, or a particular role, and needed to know how to behave for an audit. Some wanted to know what was expected on an audit, some were new to the auditing experience, for some this was training in how to conduct internal company audits. Some were coming up for an audit, for some it was a refresher, and for some like myself had been exposed to audits, but had never had any formal training on what was expected.



The first session opened with Natasha Gibbs, who talked about, what an audit is, it's aims, what an auditor would expect to look for on a micro audit and how to act if you're the auditor.

Andy's session was on essential behavioural skills. This included lively role-play to explore different questioning and answering techniques and to show how important it is to make sure you've understood what it is the auditor wants.



After lunch, Paul Lovegrove-Saville, led an interactive session looking at general factory and micro lab issues that might come up during an audit. As with all PharMIG get togethers this led to a lively discussion on issues we face such as cleaning validation, environmental monitoring, media trials and water systems.

Bob Johnson's session followed on with a look at topical auditing issues. There was a useful summary of 483 observations from the last couple of years, the most common reasons for recalls, and the top 5 deficiencies seen by auditors and their comments in the last 18 months plus, a comprehensive list of detailed observations and comments from inspectors on various aspects of pharma micro and production.

The main themes of the day were summarised very well by Paul at the end of the course, when he read out a list of points relating to managing an inspection

- Have a Control Room which is manned at all times
- Have people to document what is being looked at by the inspectors
- Take copies of documents requested by inspectors
- Have runners who can get documents in a timely, efficient manner
- Clarify any issues with the auditor at the end of the day
- After the auditor leaves have a feedback session to sort out issues
- Try to get relevant info, such as EM, water systems, action reports, etc in the control room,
- Before you present anything to the inspector, read it first
- Prepare your defence before hand on contentious issues
- Find out as much about the inspector before hand they may have pet subjects you can prepare for
- As inspectors have the authority to turn up unannounced, have a procedure/ back up system in place
- Remember you're the expert, so don't get intimidated
- Be confident, and project the right image
- Maintain a high degree of professionalism
- Ask for clarification, if you don't understand anything
- And finally the best way to be prepared for an audit is.... preparation, preparation, preparation!

This ended a really useful, informative day.

Trudy Adjrah
Roche Products Ltd

Date for your diary's -

Surviving a Microbiological Audit will be held on April 24th 2003.
The full programme is outlined opposite

Thoughts on Microbiological Limits in the European Pharmacopoeia

by Nigel Halls NHC-Nigel Halls Consulting

It's not often I have the spare time to think about the microbiological limits in the European Pharmacopoeia and when I do have the time I never seem to reach a firm conclusion... didn't someone say something once about a camel being a horse designed by a committee?

One of my favourite puzzles has been trying to find a reason why the limits for the TAVC (PhEur 2.6.12) say that a limit prescribed in a monograph as being not more than 102 microorganisms per g or mL shall mean the maximum acceptable TAVC shall be 5×102 , and the same "uplift" principle applies for a limit of 103 per g or mL.

Let's look at the test, which starts with dissolving 10 g or 10 mL in 100 mL of a neutral diluent. For the much loved Pour Plate technique you then prepare serial dilutions and plate 1 mL in duplicate (at least) Petri dishes. This is to be done in both CSDA and in SGA.

If we plate 1 mL of the "parent" preparation without further dilution, we would be putting the equivalent of 0.1 g of product in each Petri dish. So, if the product were to be contaminated with exactly 102 bacteria per g we would expect to count ten colonies after incubation. So far, so good, this would "pass" the test. But what the pharmacopoeia says is that we could count up to 50 colonies on the plate after incubation and still "pass" the test. Now, there's excuses for lack of precision in techniques, there's excuses about biological variability, there's excuses about heterogeneous distributions (this, by the way, is dealt with elsewhere in PhEur) but surely there's no sound argument for 50 colonies on a plate being of no more significance than 10?

You might say, well PhEur has proposed this to accommodate variability at greater dilutions. Of course, you shouldn't have done this, but where there's folks there's mistakes. So fair enough, you've made an extra dilution and 102 per g is represented by one colony per plate after incubation (or two colonies on one plate and zero on the other – there's no other combination that counts out at 102 per g). Sampling statistics come into play – each one mL plated is not necessarily going to contain one colony forming unit, some 1 mL aliquots will have none, some one, some two, some three and so on. A bright statistician could probably tell you how probable it is to find 5 colony forming units in a 1 mL aliquot of a homogeneous solution or suspension in which the mean concentration is 1 colony forming unit per mL, I don't know exactly what it would calculate out at but I do know it would be the best part of nothing at all. So sensibly we can discount sound statistical reasons being behind the "uplift".

Equally well we should be able to discount laboratory contamination as a reason. The odd technique-related colony - yes we have to expect that, but up to five times as many as there really are in the product; surely that's incompetence ?

Then we must think about more sophisticated reasoning to account for the "uplift". The TAVC according to PhEur is the sum of the bacterial count and the fungal count. If we did not have the "uplift", then a bacterial count on or over the limit would result in a failed test even if the fungal count were zero, and vice versa.

Sounds a bit tough perhaps, especially with "too much dilution", but with the "uplift" in place both bacterial and fungal counts could be individually well over the prescribed limit and the result would still comply. I can see why you might want some sort of "uplift" to accommodate the practicality that counts on Casein Soy Bean Digest Agar and Sabouraud Glucose Agar are not always in practice mutually exclusive but surely not to the extent of a multiple of 5.

I am of the opinion that there are enough errors surrounding quantification of numbers of microorganisms in pharmaceutical preparations to merit some flexibility around limits. I'm also of the opinion that the principle of the "uplift" is quite a good idea to accommodate this, but PhEur has gone too far by making a 102 per g or mL limit mean 5×102 , and a 103 limit per g or mL mean 5×103 .

I would suggest that an "uplift" by a factor of 1.5 would be quite sufficient. In other words when a limit of not more than 102 microorganisms is prescribed in a monograph the maximum acceptable TAVC shall be 1.5×102 , and when a limit of not more than 103 microorganisms is prescribed the maximum acceptable TAVC shall be 1.5×103 .

This would mean that when a limit translates to an average of 10 colonies per plate, you would allow averages up to 15 colonies per plate – generous but not over generous. With "too much dilution", a limit which translates to an average of 1 colony per plate you would allow an average of 1.5 colonies (two colonies on one plate and one on the other, or three on one and zero on the other). Sounds reasonable to me.

Why is no-one else rabbiting on about this ? Well, I guess it's because with pharmaceutical preparations the likelihood of having a TAVC anywhere near the limit is so extremely remote that the idea of the "uplift" is rarely or ever invoked. But is this a good enough reason for bad science ?

Well, it's only our reputations that are at stake. If you can justify the uplift by a factor of 5 please tell me and I'll eat humble pie.

Keep on streakin' - Nigel Halls

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PharMIG Conference 2002

By Lisa Wood - GSK, Beckenham

This was my first PharMIG conference and I was not sure what to expect as I entered the Moat House Hotel Peterborough on a cold November morning. I was therefore pleasantly surprised to be greeted by a crowd of friendly faces and people who all had the same interest as me... Microbiology. We had gathered together to partake in the 2002 PharMIG conference on Quality Challenges in Pharmaceutical Microbiology and I was very interested to find out what the next few days had to offer!



On entering the conference facility we were met by numerous tabletop exhibitions covering a wide range of suppliers. There were plenty of opportunities to peruse the stalls and discuss technical issues with the representatives and even pick up the occasional souvenir (pen, pocket calculator, and even a sports-style rucksack if you had the nerve to ask).

The conference hall was excellent with an eye-catching stage and superb facilities. Chairman David Begg opened with an enthusiastic and warm welcome reiterating the importance of managing every aspect of quality in pharmaceutical microbiology. We were, as David explained in for a treat as we had a number of highly specialised expert speakers from as far and wide as Holland and Switzerland as well as the UK. We would also be able to participate in round table discussion groups lead by experts where we could discuss in detail more specific topics. David also took time to make a special welcome the youngest member of PharMIG, 1 year old Eleanor.



Dr Werner Hecker from NOVARTIS Pharma in Switzerland conducted the first lecture. He spoke about the challenges he has experienced in the Pharmaceutical industry over the past 30 years and the changing views in Microbiology. His informative speech touched on many issues, including the problems relating to media fills from an inspection point of view, use of isolators and trend analyses. He concludes that even as many of the skills of a microbiologist have remained the same, the job of the microbiologist nowadays has a much more integrated role in pharmaceutical operations.

Jolanda Schoemaker spoke on out-of-specifications and re-tests in microbiological laboratories. Her speech was full of good practical examples and she had an engagingly energetic style, which kept the audience captivated. Jolanda showed us how a simple but effective investigation procedure could be implemented in any out-of-specification situation.

Martin Lush followed with a clear, concise and comprehensive speech on Microbial Evaluation of raw Materials and Non Sterile Products. Martin discussed the importance of good microbiological control and he reiterated the importance of the microbiologist getting out of the lab and into the facilities. He suggests that we will never achieve a genuine perception of contamination levels or poor working practices by examining plates alone. This I feel is a very important piece of advice as we as microbiologists sometimes feel that our place is locked away in the laboratory.

After a quick lunch and a chance to mingle with other delegates or attend one of the three round table discussions sessions it was back to the conference hall, with the hope that the afternoon held as much interest as the morning. Stewart Green of Wyeth Pharmaceuticals showed a wealth of knowledge and ideas on his chosen topic of Risk Assessments. Stewart's process of risk characterization was fascinating and as he explained takes in to consideration hazard identification, hazard characterization and exposure assessment. This could be applied to each element of the manufacturing process and he states is an inspectable process, which will help to set priorities and identify possible contributory factors.



My views on the scientific community were dramatically altered at the conference dinner and dance. After a hearty feast and one or two drinks the dance floor opened and was quickly filled with disco divas and John Travolta's strutting their stuff.

After a well-rested night (for some, if not all) and a few cups of coffee we were ready for the second day's activities. The discussion groups were relaxed, engaging and informative. They were the perfect opportunity for delegates to ask questions and obtain detailed advice on specific technical topics. The topics discussed were Current Practices in Pyrogen testing, Validation Issues and Microbial Quality in Non-sterile Manufacturing. I will note that the groups were well represented, perhaps overly so as occasionally it was hard to hear comments especially in the group situated in the large hall.

Gordon Farquharson a chartered engineer with more than 20 years experience in the field, delivered the first lecture of the day. He spoke on improvements in new and existing facilities and he showed a high degree of knowledge and expertise in the application of EU GMP and USA FDA cGMP requirements. The use of Isolates was a reoccurring theme throughout the two-day conference. Many issues were raised including costs, space, bio-decontamination and environmental sampling techniques. Gordon closed this topic by saying "Never before in the history of sterility assurance has so much been written by so many, so often about such a simple concept" - and who am I to disagree.

Paul Hargreaves of the MCA gave the last lecture of the day on training. His creative use of audience participation helped spice up the final lecture (otherwise known as the graveyard shift) and kept the waning crowd interested. Paul demonstrated that training must be challenging, exciting, interesting and fit for the purpose required. At the end of an exhausting two days we left the Moat House hotel with our heads stuffed with valuable information and acquired knowledge, our pockets with numerous pens and other souvenirs, and stomachs with far too much food and drink. All in all a very satisfactory experience.

Lisa Wood
GSK, Beckenham

PharMIG NON STERILE MONITORING SURVEY

PharMIG Non-Sterile Monitoring Action Group Members

- Susan Edwards (Roche) Action Group Co-ordinator
- Amanda Lund (Boots Contract Manufacturing)
- Julian Kay (GlaxoSmithKline)
- Janet Berryman (Lilly)
- Alison Warner (GlaxoSmithKline)
- Catherine Orogun (Lonza)

Introduction

The Non-Sterile Action Group was re-started after the Pharmaceutical Microbiological Interest Group (PharMIG) 2001 Conference. It was apparent that there is still a lot of variability in what the industry as a whole is doing with regards to Environmental Monitoring in the wide area Non-Steriles. The Action Group was made up of six members from five companies to try to find out what the industry is doing so that we can try to evaluate why.

The questionnaire was distributed to all PharMIG Members and this document is a collation of the 27 replies. This questionnaire is the first from the Action Group and this information was presented at the Joint PharMIG and POG meeting held on the 28th January. This questionnaire has already generated interest in the MCA and we hope to gather further information to help contribute to a PharMIG monograph in this area.

The aim of this group is to act on behalf of the PharMIG on any issues concerning Non-Sterile Environmental Monitoring.

Thank you to all whom to the time to help contribute to the results.

Natasha Gibbs (Action Groups Co-ordinator)
Sue Edwards (Non-Sterile Action Group Co-ordinator)

Do you perform non-sterile monitoring?

Yes	No	No response
22	3	2

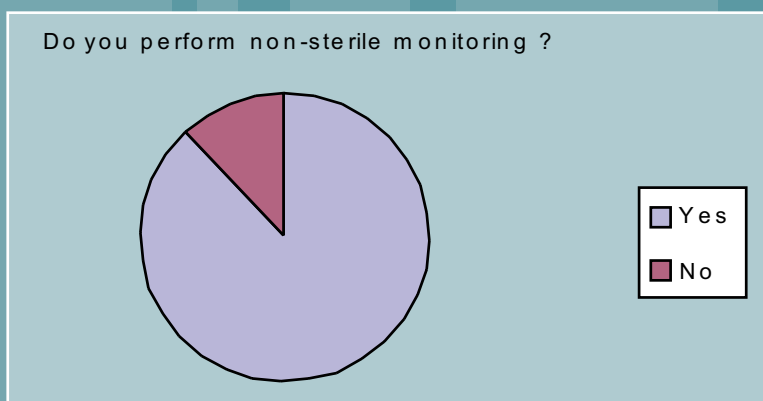
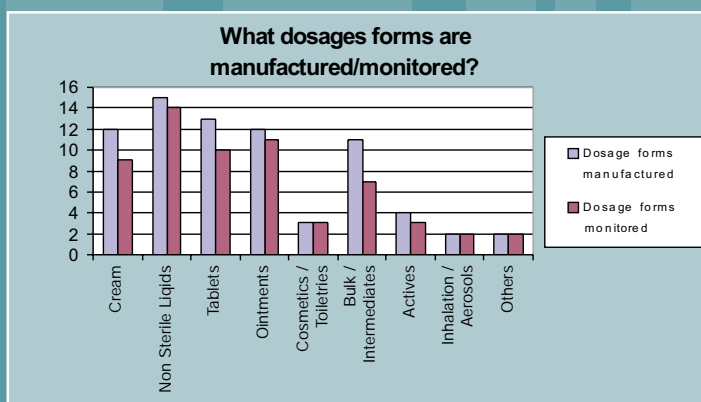
Reasons for not monitoring

- Differing opinion in various departments
- A development facility only

Would you consider performing non-sterile monitoring in the future?

- Comments: - Know there is a need, will be implemented in future.

1. Monitoring Process



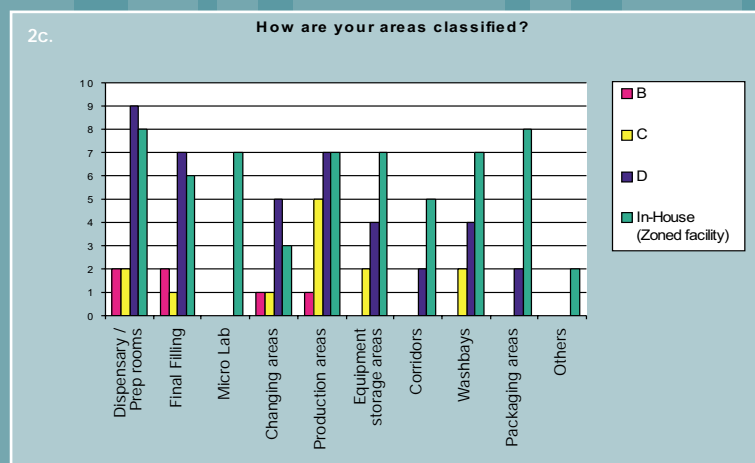
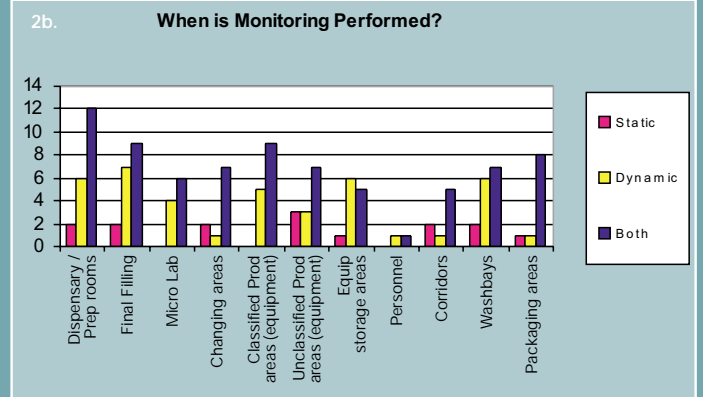
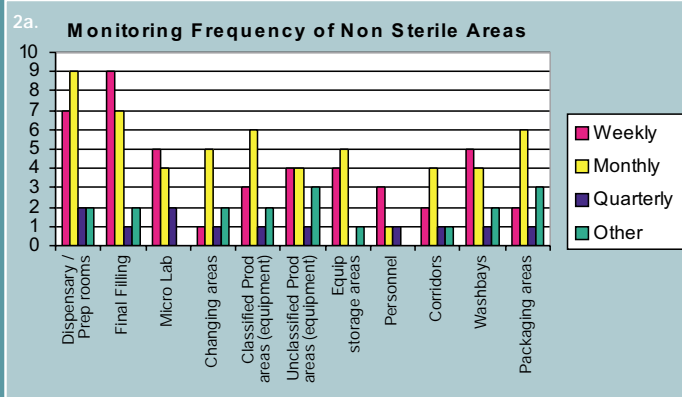
Does your company encounter any problems with dynamic monitoring?

- Various comments on people affecting results
- Toxic materials present, need clean down before monitoring
- Can not monitor equipment whilst running

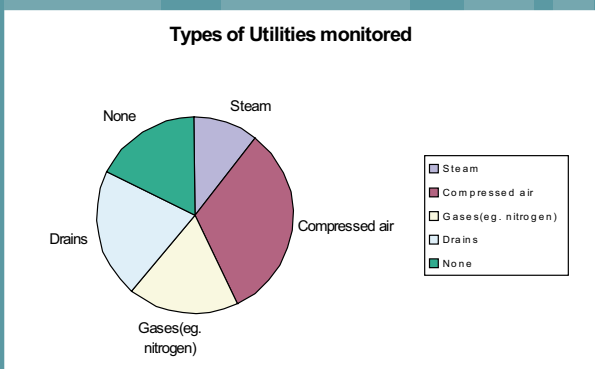
How do you choose your monitoring positions?

- Risk assessment
- Proximity to product contact
- Areas of vulnerability e.g. drains
- Commissioning studies (validation)/review of area
- Maximum activity time in areas

2. Monitoring Regime

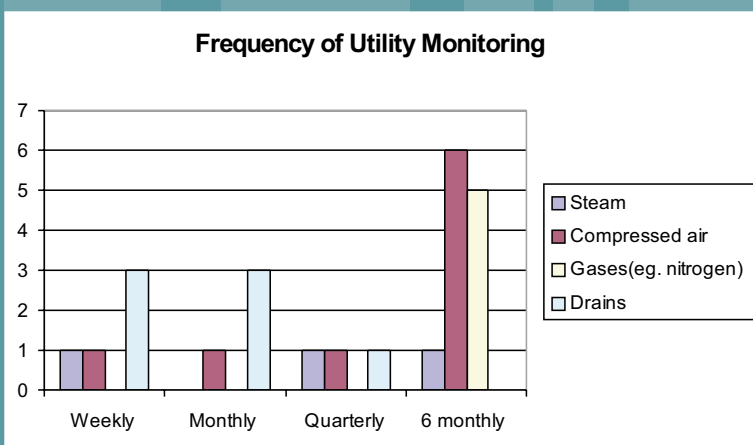


Utilities Monitoring

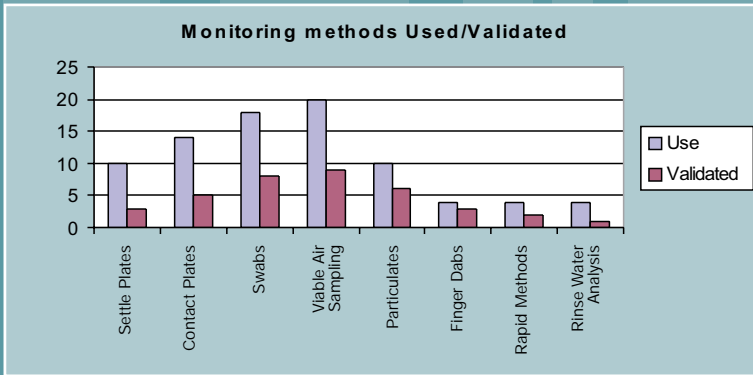


Comments

- Some tested at commissioning, not since
- Another utility mentioned in replies was monitoring of cleaning equipment e.g. mops, buckets



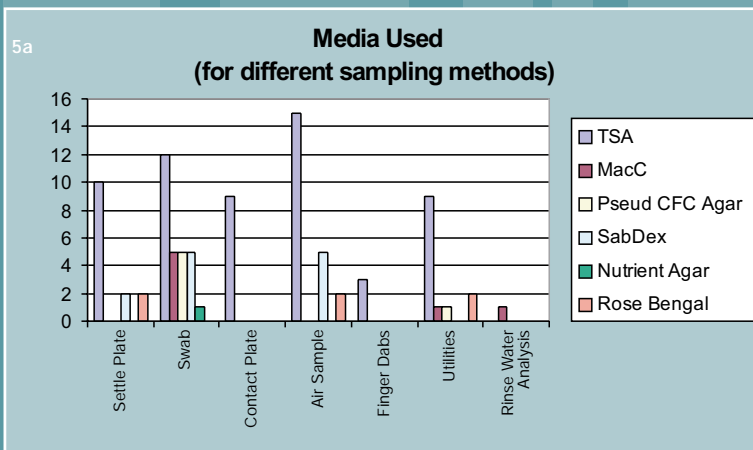
4. Methods



Rapid methods used

- Hylite
- Bioluminescence
- RABIT blocks

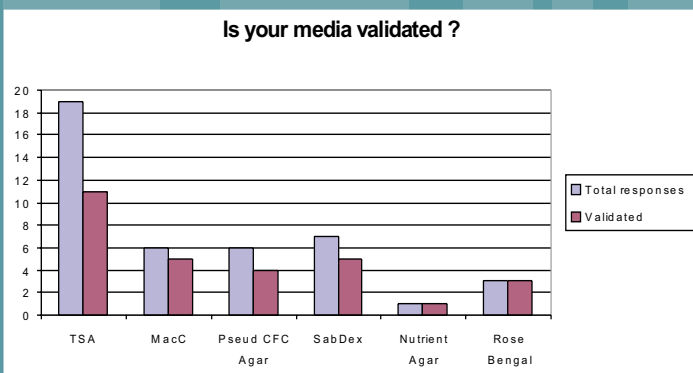
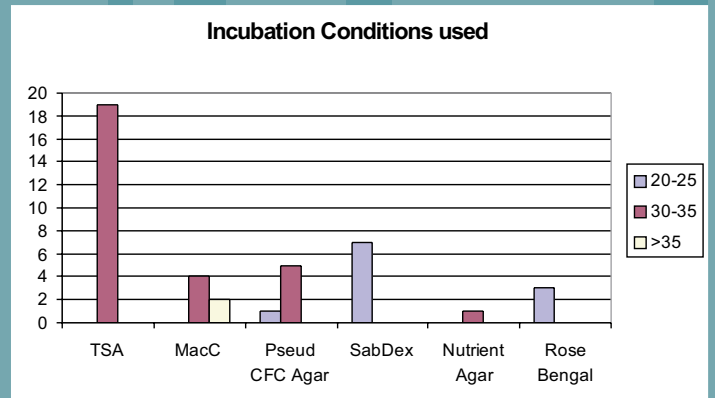
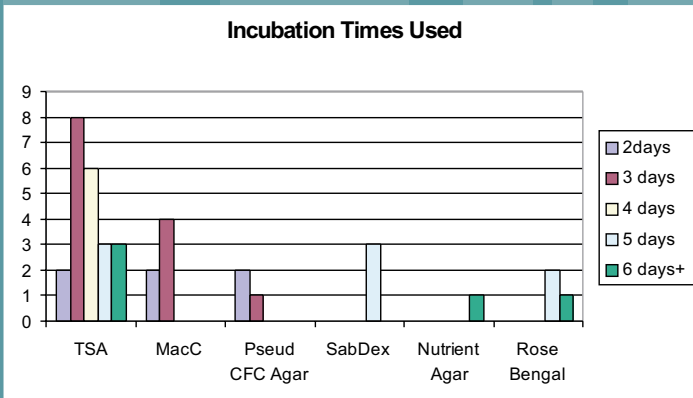
5. Media



Other:

DE Neutralising Agar, Lethen/Tween Agar, TSB, WIB, Yeast Extract Total Count, Plate Count, Baird Parker Asparagine Broth (+ethanol), SPC Agar, TPC Agar

5b.

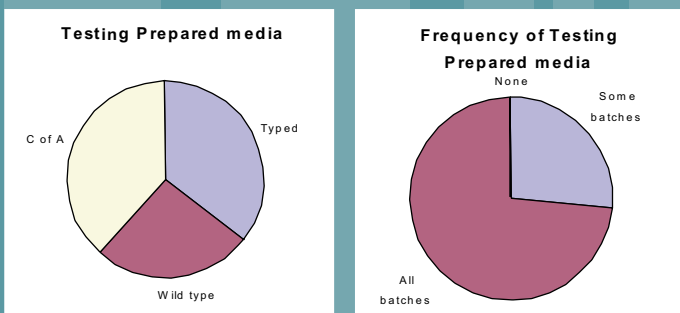


Comments:

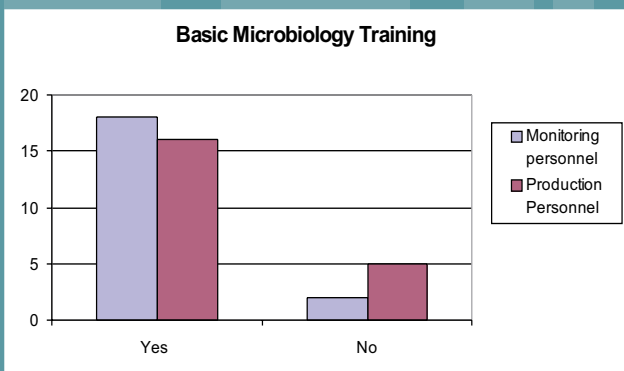
- Bought in prepared media is initially validated and tested, with sufficient data routine testing is decreased/stopped.

5 c.

How do you test your media? Do you use typed/wild type organisms or use C of A?



6. Training

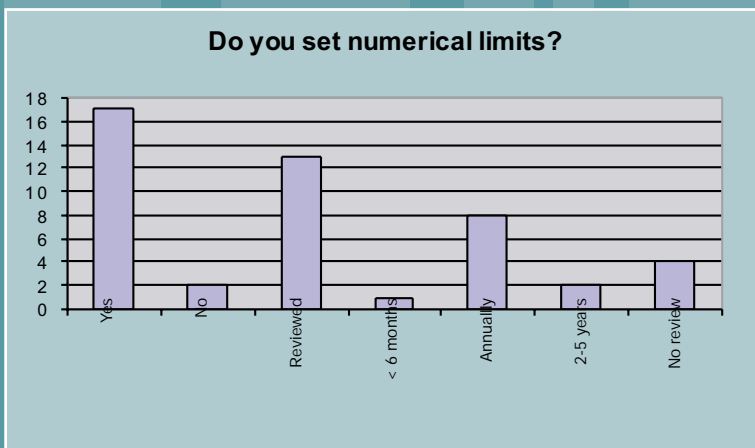


Comments: What kind of training is provided?

- Basic dos/don'ts
- Aseptic technique
- Basic hygiene training
- Basic Microbiology
- Refresher training
- Annual microbiological awareness for production staff
- GMP (packaging, engineers)
- Microbiologists do most of the monitoring

7. Limits

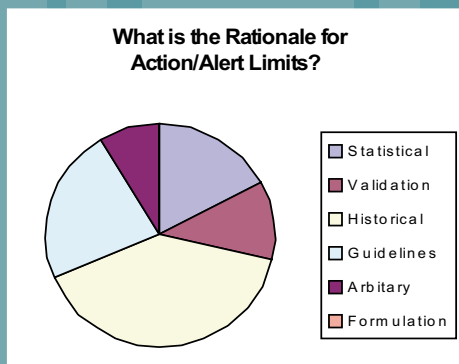
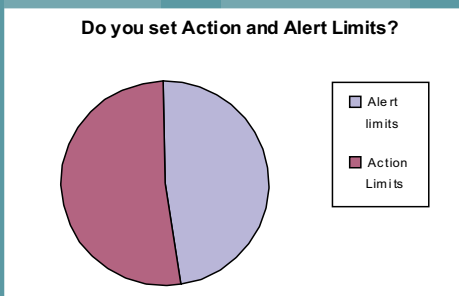
7a. Do you set numerical limits?



Comments: How are limits set and reviewed?

- Orange guide (use Class D)
- Monitor for 10 consecutive days, results collated and averaged, limits set from this
- Corporate guidelines
- Commissioning studies
- History and Pharmacopoeia
- Validation exercise
- Qualitative assessment, e.g. 'good', 'bad'
- Annual review/historical data (including OOS)
- Statistical (3 months data plus Standard deviation), reviewed

7b/c. Do you set Action and Alert limits? What rationale is used?

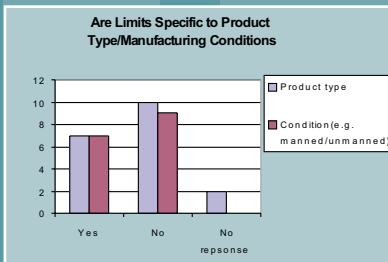


7 d/e. What do you do if the Action/Alert Limits are exceeded?

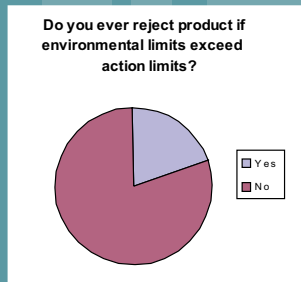
Clean area
 Re-monitor (within 48hrs)
 Test/Assess product
 Review other data
 Assess contamination/product
 Inform production/QA
 Quarantine equipment/product
 Increase frequency of monitoring
 Make note
 Deviation (IR) raised, ID & 3 sequential monitoring sessions
 "2 x alert = action
 Look at trend/Gram stain

Action	Alert
✓	
✓	
✓	✓
✓	✓
✓	
✓	
✓	
✓	
✓	✓
✓	
✓	✓
✓	✓

7 f.



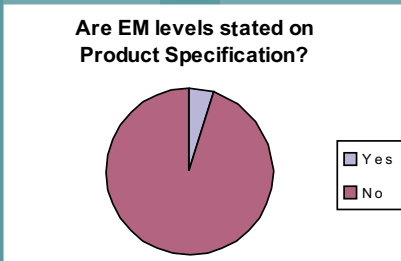
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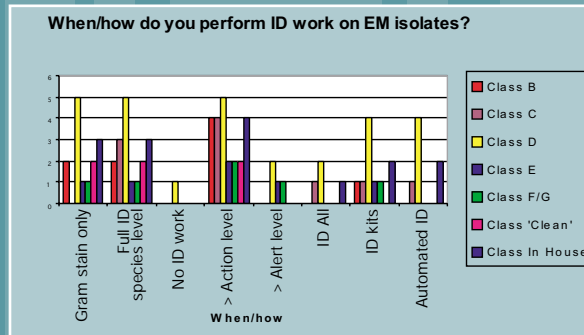
Comments: If yes, describe the circumstances under which this might occur.

- If an investigation found risk to product then reject
- Critical incident, quarantine batch the reject
- If high level of contamination is reflected in product
- Just starting to link product testing to monitoring data
- Just starting to link product testing to monitoring data

7 h.



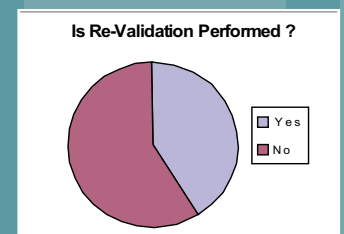
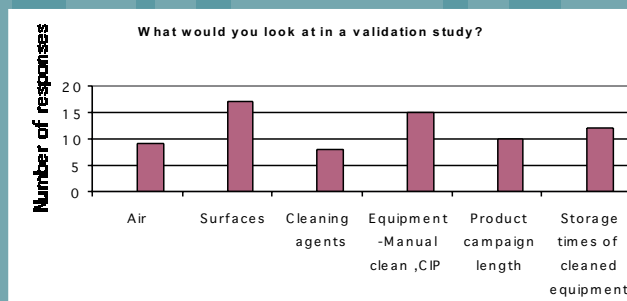
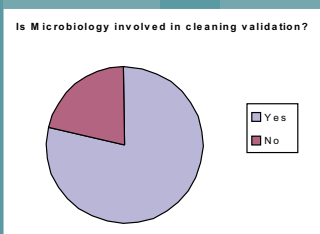
7 i.



7j. What do you classify as 'Objectionable' organisms?

- Pathogens • Enterobacteriaceae • Pseudomonads (aeruginosa & fluorescens) • EP named organisms
- Change in proportion seen e.g. increase in organism type/count • E coli (Coliforms) • C albicans • Staph (aureus)
- Organisms that could cause product spoilage • Cause disease • Anything that is identified • Streptococci
- Depends on product/type of monitoring • Gram negative bacilli

8. Cleaning Validation a,b,c



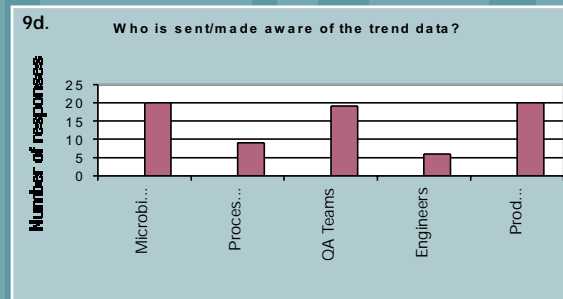
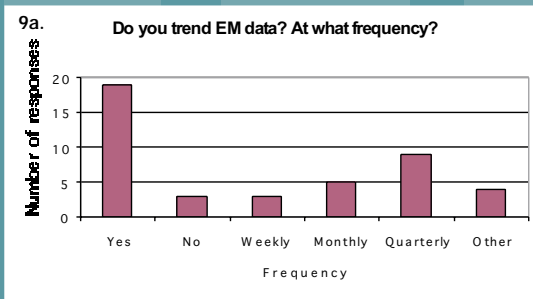
Comments: The frequency of revalidation periods were given as: -

- Annual • Every 5 years • 3 yearly review

8d. What acceptance criteria/limits would you choose?

- Alert/action limits, historic and Standard Deviation
- Absence of organisms as required in the product test
- Risk assessment – absence
- EM limits used routinely
- In house standards < 50cfu/4x4 square/swab
- Absence of Gram negative organisms
- CIP – low level of Bacillus/Staph spp, absence of Gram negative bacilli
- <50cfu/swab (6x6 sq. cm)
- <100cfu/swab
- <100cfu/25sq cm
- = Class D limits
- Absence of Pseudomonas/Enterobacteriaceae
- Worse case looking at surface area (size of equipment)

9. Data Trending



9c. What do you think constitutes a trend?

Comments: None

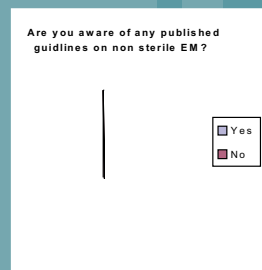
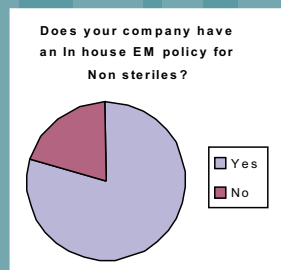
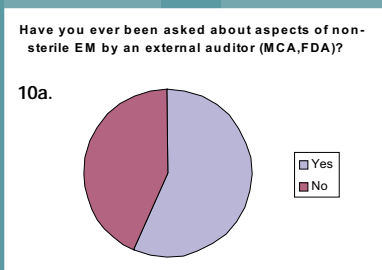
9f. If you use statistics, what do you use?

- Very little statistics is used in EM
- Used to reduce limits

9g. How do you treat datum point recorded as TNTC or Uncountable when compiling trend data?

- >300cfu/plate
- 500cfu/plate
- excess therefore exceed action limit
- Pick a high number that is obvious on the graph
- = or > action limit
- TNTC not included in numerical trend, used in visual

10. Regulatory



Comments:

- All quoted sterile guides e.g. orange guide

10d. What is the value of Non-sterile Environmental Monitoring?

- Demonstrates control
- Can answer issues on product status, answers on environment can be given
- Important if no end product testing is done
- Useful for requests from customers
- Can see if cleaning regimes, HVAC is sufficient
- Aware of organism population, can see changes
- Susceptible areas for production awareness
- Indicator of quality
- Added information for OOS breach/product specification
- Ensures maintenance of area cleanliness
- EM does not ensure area cleanliness, need good GMP
- 'Snap shot', not good GMP

10e. Is some kind of risk analysis more valuable?

(Is HACCP/FMEA performed for example)?

- For aseptic products only
- Risk analysis as basis for EM programme
- FMEA before cleaning SOP written
- What is HACCP/FMEA?
- Interest out there but not formally done

Comments/ what people want

- List of applicable guidelines
- Limits for each non sterile product type and areas
- Clear guidelines for all the industry
- How to determine alert/action limits, frequency of EM
- How much validation is needed for a new product facility

10a. Comments: What questions were asked?

- Asked for overview of results
- Recovery experiment to validate swabs
- If drains are sanitised/monitored
- EM programme, results and quarterly report
- Frequency of monitoring, methods and trending
- Was EM performed and were compressed gases tested
- In house audit – told to look into non sterile monitoring
- Frequency, trends and neutralisers in culture media
- Trend data

PharMIG Action Group



I hope that you all had a good Christmas break, which I personally feel, was not long enough as I quickly get back into work mode. As we move swiftly into 2003 I am waiting with anticipation to see what this year holds for developments with the Pharmaceutical industry and PharMIG.

The US Senate Health Committee will be pushing for changes in the FDA's approach to vaccine regulation. One of the things they want to do is look at FDA to do a top-to-bottom review of what it is

that's slowing up the vaccine process," the Republican staffer said. The Committee wants FDA to look at "the review process, the approval process and also how they communicate with industry."

This can only be a good thing to help speed up getting vaccines to the market place especially as most vaccines currently have only one or two manufacturers. Therefore, a decision by a manufacturer to withdraw its product from the market could lead to a shortage, as happened last year with the influenza vaccine.

In light of this I would like to have volunteers to start up a BioPharmaceutical Action Group to help look at what the industry is doing and ways to improve the efficiency of the microbial control of Biotech processes and testing. The Current Action Groups are continuing to produce important data, so this Group will run alongside them.

The Non-Sterile Monitoring Group have collated the data from their first questionnaire and received a very good response from the PharMIG Members. Julian Kay at the joint PharMIG and PQG meeting held on the 28th January 2003 presented the results from the survey. These had already received interest from the MCA, so we can expect good things from the Non-sterile Action Group this year. If you have any queries on the results obtained then don't forget to utilise the PharMIG forum on the webpage.

The Bacterial Endotoxin Group leader Lynne Arnot has been working with the Parenteral Society to produce a joint monograph and we eagerly look forward to the publication of this document. Trudy and her team on the Disinfectant Action Group have been working hard on their sections for their monograph. This is now at the editing stage. Richard Benton has kindly offered to co-ordinate the Water Activity Action Group.

I look forward to what the Action Groups have to offer. The Action Groups are dynamic and do accept new members. If you would like to know more information about any of these Groups, or would like to participate in one then please contact myself on agc@pharmig.org.uk.

Wishing you all a prosperous New Year.

Natasha Gibbs
Action Group Co-ordinator

DIARY DATES PharMIG - events schedule for 2003 (Draft)

1st April

Site visit to: CP Pharmaceuticals

1 Day Visit

24th April

Surviving a Microbiological Audit

1 Day Meeting

May

Method Validation & Micro Methods

1 Day Meeting

June

A3P meeting 3rd & 4th - France

(2 talks represented by PharMIG)

2 Day Meeting

June/July

Sterilisation & Irradiation - Microbiological Issues

2 Day Meeting

September

Practical Training on Cleaning & Disinfection - Bath

2 Day Training Course

October

Engineering for Microbiologists

1 Day Training Course

November

PharMIG 2003 Conference

2 Day Conference

December

Rapid Microbiology Techniques

1 Day Meeting

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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(Email) info@pharmig.org.uk