

PharMIG

The Pharmaceutical Microbiology Interest Group

News

Issue 5 August 2001



Repeatability and Precision - Necessary Factors in Standard Testing?

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Introduction

In the last edition of PharMIG news I wrote an article which applied assay performance characteristics, more often associated with analytical techniques, to a microbiological method (the automated LAL test). In this piece I want to again consider issues of repeatability and precision, but in this instance, to apply them to a test requiring a high level of person input.

I would imagine that some readers are already scratching heads. Is it correct to try and qualify an individual as well as a machine? Or are we being driven to further extremes by inspectorate demands? What is required as part of a basic training package for a microbiological analyst? These are issues for debate, and perhaps PharMIG should again consider issues surrounding training.

The example that I wish to explore is the pour plate technique. A simple, long established technique for performing the total viable aerobic (bacterial or fungal) count, and one that is practised in most microbiology laboratories.

In this test the Petri-dishes are standard (often 9 cm diameter), the pipettors uniformly manufactured and straightforward to verify, the volume of sample added and the amount of agar and degree of mixing can be standardised. However, errors can still arise and a common problem is the need to raise an out-of-specification report when duplicate plates have wide differences in counts (by 'wide difference', the USP <1227> recommendation of a not greater than 70% difference is a useful guide).

If regular problems occur, such as, if the sample is not considered to be the problem can they be addressed through training' (using the classic 'try-show-do' approach) and visual assessment? Is this enough?

A statistical check could be introduced. One test to explore is a test for repeatability.

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Happy 10th Birthday
PharMIG, wishing
you many more
successful years from
DiverseyLever Ltd.

Weston Favell Centre, Northampton NN3 8PD Tel: 01604 773135 Fax: 01604 783446

repeatability

By repeatability I mean a test to determine the accuracy of an individual's pipetting for replicate plates from a given uniform sample.

Such a test could involve taking a neat culture of a readily used micro-organism, such as *Staphylococcus aureus*, and diluting it down until a solution with an expected count of 25 - 250 cfu/ml is obtained. 25 - 250 being the often quoted optimum range for the counting of pour plates, avoiding error at the lower end and confluence and over-crowding at the upper.

The individual would then be required to pipette ten aliquots (of 0.1 or 1.0 ml) into 10 Petri dishes, add agar (TSA or PCA), mix and incubate for 48 hours. After incubation the plates would be counted and then statistically examined for significance. An appropriate significance test would be Chi-squared (χ^2). χ^2 is a statistical test used to analyse frequency data and measures the deviation of a score from its population mean divided by the population variance.

The end result can be checked against significance tables. The degrees of freedom would be 9 (in this case of 10 replicate plates) and a probability of 5% would be appropriate given the small degree of variance in such a manual test. If the obtained variance were 'not significant', the individual would pass the test. If, on the other hand, the variance was 'significant', re-training could commence and the significance test repeated as one way of measuring the effectiveness of the training.

An example, using a technician at BPL, is illustrated below.

Technician: Victoria Pettifer
 Micro-organism: *Staphylococcus aureus* (ATCC 6538)
 Dilution plated: 10-6

results

Plate	Count (cfu/ml)	Observed - Expected count (X - K)	(Observed - Expected) ²
A	99 (A)	3	9
B	100 (B)	4	16
C	87 (C)	9	81
D	87 (D)	9	81
E	96 (E)	0	0
F	85 (F)	11	121
G	119 (G)	23	529
H	91 (H)	5	25
I	97 (I)	1	1
J	97 (J)	1	1
Mean count (K)	96* (K)		Total (V) = 864



* = Rounded up from 95.8

$$\chi^2 : \frac{V}{K} = W \quad \frac{864}{96} = 9.000$$

From χ^2 tables, with 5% probability and 9 degrees of freedom, if W is less than 16.919, then the obtained result is not showing significant variance (i.e. a pass); if W is greater than 16.919 then there is significant variance (i.e. fail).

The obtained result of 9.000 is a pass.

Such a test could be run at regular intervals (for example, six or twelve monthly) as part of technician re-qualification.

precision

The above test will give the laboratory confidence in the individual performing the test. However, the issue of day-to-day variance between replicates can still arise. How much variance is significant?

Earlier, the 70% difference was mentioned. Using a 50% or 70% difference is a useful approach, however, one question that arises is difference between what? The first plate and the second? Which is the 'true' result of the sample? Another approach could be the use of confidence intervals, although this can become complicated, not least in converting Poisson distribution to normal for many microbiological samples. Coefficient of variation or standard deviation is another possibility and could be used to establish the precision of a method. However, it is unlikely that this would be used on a daily basis as this would require several replicates to be truly significant.

An alternative approach could be the establishment, by the technician, of their own precision range on a monthly interval. For example, in a similar way to the repeatability study above, a micro-organism could be taken and added to 10 - 15 samples of a diluent (at a concentration expected to yield a countable range - 25 to 250 cfu/ml).

Each of the 15 samples would then be plated out in duplicate (into plates labelled D1 and D2), agar added, mixed and incubated for 48 hours. After incubation the plates would be counted.

The counts for D1 and D2 could then be converted into logarithms. If the result for either was zero, 1 should be used to calculate the log. Following this, for each sample, the range would be calculated (Rlog), the ranges summed, the mean of the ranges calculated and precision criteria set using an appropriate constant.

The routine test plates for the technician could then be compared on a daily basis.

conclusion

This article's main intention is to stimulate thought. The approaches described carry the risk of adding to already over-burdened laboratories and the danger of applying a false degree of accuracy to what are manual and relatively imprecise techniques, which could lead to unnecessary rejects or failures. The pour plate can, at best, only give an estimated count.

However, reliability of methods and supported in-house training are areas likely to be probed for by auditors. How far would you go?

references

AOAC (1992): 'Standard methods for the examination of Water and Wastewater', 18th edition
 Hinton, R. (1995): 'Statistics Explained', Routledge
 PDA Technical Monograph No. 33





May we take this opportunity to wish you a Happy 10th Anniversary and to wish you the very best for your continuing success in the future.

Grafton Way, Basingstoke, Hants RG22 6HY
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Conference 2001

Wednesday 7th & Thursday 8th November 2001

Peterborough Moat House Hotel

Conference 2001 is a fitting venue to celebrate our 10th anniversary in fine style. The range of technical presentations will be given by an outstanding selection of international speakers. PharMIG is especially fortunate to have Dr Bob Morrissey from Johnson & Johnson in the USA as our special guest speaker. In addition, we are delighted to welcome back Dr Nigel Halls and Dr Peter Gilbert, both of whom are staunch supporters of our organisation. As usual, we can rely on Nigel and Peter to provide some incisive and thought provoking views! From the MCA we are pleased to welcome for the first time, Mr Andrew Bill who will guide us through the latest news on Parametric Release to be followed by hot debate in the Open Discussion Session led by Sharon Johnson. Our last speaker of the Conference, Dr Manish Parekh, has agreed to fly all the way from Chicago to enlighten us on bioprobes.

The Conference will provide the opportunity for the Action Group Leaders to present the results of their hard work.

The enthusiasm and energy of our Action Group Members has resulted in the compilation of some extremely valuable data and information across a range of subjects. The opportunity for the Membership to hear at first hand about the work of Action Groups is long overdue.

As on previous occasions, our Conference offers a golden opportunity for Members to meet each other and to benefit from a first class professional forum. Equally important is the time spent discussing common issues, exchanging ideas, networking and of course, having just a little time out enjoying the now traditional entertainment which is part of the PharMIG Conference.

To book a place or for further information, please contact Poly at PharMIG on 01992 478675 or poly@pharmig.org.uk

PROGRAMME WEDNESDAY 7TH NOVEMBER

09:30 - 10:15	Tea/Coffee and Registration
10:15 - 10:30	Chairman's Welcome and Introduction Mr. David Begg * ^C PharMIG Chairman
10:30 - 11:30	Key Note Lecture The Vision for Pharmaceutical Microbiologists SPEAKER 1: Dr. Robert F Morrissey
11:30 - 12:15	Cutting Edge Issues for Pharmaceutical Microbiologists SPEAKER 2: Dr. Nigel Halls
12:15 - 13:45	EXHIBITION & Finger Buffet Lunch
13:45 - 14:30	Molecular Microbiology: W(h)ither Physiology! SPEAKER 3: Dr. Peter Gilbert
14:30 - 15:00	EXHIBITION with Tea & Coffee
15:00 - 16:00	Action Group Reviews SPEAKERS 4,5 & 6 (see over)
16:00 - 16:30	Panel Discussion and Close
16:30 - 17:30	AGM (Members only)
19:00 - 20:00	EXHIBITION including Pre-dinner Drinks and Canapés
20:00 'til Late	Conference Dinner & Dance (Smart Attire Required)

PROGRAMME THURSDAY 8TH NOVEMBER

09:00 - 09:15	Chairman's Remarks Mr. David Begg * ^C PharMIG Chairman
9:15 - 10:00	Parametric Release – Myth or Reality? SPEAKER 7: Mr. Andrew Bill
10:00 - 11:15	Open Discussion Session (See overleaf) Sessions 1, 2, & 3 running concurrently
11:15 - 11:45	EXHIBITION with Tea & Coffee
11:45 - 13:00	Open Discussion Session (See overleaf) Sessions 1, 2, & 3 running concurrently
13:00 - 14:15	EXHIBITION & Lunch
14:15 - 15:00	Rapid Methods in the 21st Century - Utilising Molecular Biology & Biochips SPEAKER 8: Dr. Manish Parekh
15:00 - 15:30	Open Discussion Session
15:30 - 15:45	Summary and Close of Conference

chairman's review



Whilst July 26th was PharMIG's official 10th Anniversary, it is our Conference in November that offers the opportunity to mark this event. To say that PharMIG has achieved much in its 10 short years is indeed an understatement!

Looking back it is remarkable that nine very successful Conferences on a wide variety of topics have been organised, and no doubt our 10th will be equally successful. Other activities in our first decade include many meetings covering a range of specialised topics, joint symposia with other professional bodies, company visits, links with regulatory bodies and, of course, the all important Action Groups which are now delivering extremely valuable practical information. Nor should we forget the splendid work done by Martin Sarosi (an adopted PharMIG Member!) in producing a superb Web site.

However, these achievements don't happen by accident. They are the result of a lot of hard work, commitment and dedication by many people within PharMIG. Our Group has grown rapidly and now enjoys a well-earned reputation for high quality meetings and conferences focussed clearly on pharmaceutical microbiology.

The next 10 years will provide many challenges to PharMIG, not least of which is to maintain the momentum and build on our achievements.

I believe this needs two key elements; careful succession planning to bring new people into the Committee and firm leadership to ensure that PharMIG never departs from its raison d'être – representing and promoting the interests of microbiologists working in the pharmaceutical industry. Increased work pressures on an individuals time are a potential threat and I would urge more people to come forward and offer help – either by standing for Committee positions or simply offering to assist in the many activities as best they can.

Keeping up to date is another challenge we need to face up to; not only in technical areas but also in the broad field of regulatory affairs, which at times looks like a minefield! I believe that we will also face more competition from other technical and professional groups in the future, but a determined effort to plan ahead and stay loyal to our core values will continue to deliver quality and value to the Membership. Financially we are in very good shape and maintaining a sound financial basis is vital if we are to explore new avenues in providing tangible benefits to our Members and the pharmaceutical companies for whom they work.

In conclusion, may I take the opportunity on behalf of all PharMIG Members to thank so many dedicated individuals who have contributed to our success in the last decade.

Here's to success to PharMIG in the next decade!

David I R Begg



**Congratulations on
PharMIG's 10th Birthday.
May the "Interest" grow!
From Fred Baker Scientific**

3 Lancer Court, Astmoor Industrial Estate, Runcorn, Cheshire WA7 1PN Tel: 01928 566976 Fax: 01928 580438





**Associates of Cape Cod
wishes PharMIG a Happy
10th Birthday and every
success for the future.**

3A Newton Court, Wavertree Technology Park, Liverpool, L13 1EJ Tel: 0151 220 3336 Fax:0515 220 0857

Surviving a Microbiological Audit

Wednesday 26th September 2001

Belton Woods Hotel, Grantham

PROGRAMME WEDNESDAY 26TH SEPTEMBER

09:30 to 10:00	Registration with Tea/Coffee
10:00 to 10:15	Chairpersons Welcome
10:15 to 11:15	What an Auditor would expect to find in a Microbiological Audit
11:15 to 11:30	Tea/Coffee Break
11:30 to 12:30	Interactive Session A & B (running concurrently)
12:30 to 13:45	Lunch
13:45 to 14:45	Interactive Session A & B (running concurrently)
14:45 - 15:00	Tea/Coffee Break
15:00 - 15:45	Topical Issues in Pharmaceutical Microbiology
15:45 to 16:15	Panel Discussion with Speakers
16:15 to 16:30	Summary and Close

Are you daunted by the prospect of a regulatory audit that may involve microbiological issues? This course has been tailored to some of the unique issues associated with a Pharmaceutical Microbiology audit. Many real life examples will be used and the meeting has been designed to encourage discussion.

At the end of the course, delegates should benefit from discussing their shared experiences and have a better understanding of how to avoid the pitfalls that exist when experiencing a microbiological audit.

PharMIG have introduced this one-day meeting for people working in the laboratory, microbiology & technical supervisors and managers, and other Quality professionals working in both manufacturing and research facilities. Delegates will gain an insight into the unique problems facing a regulatory audit with a microbiological emphasis.

Attendance will be limited to encourage discussion during the day. A certificate of attendance will be issued to the delegates for their training records.

To book a place or for further information, please contact Poly at PharMIG on 01992 478675 or poly@pharmig.org.uk



Hydra House, 26 North Street, Ashford Tel: 01303 247577 Fax: 01303 247578

**All at MET wish
PharMIG continued
success, Happy
10th Birthday!**





MERCK
eurolab

Merck House, Poole, Dorset Tel: 01202 664544 Fax: 01202 664406

day visit

A day visit is being organised for early October to visit La Calhène in St Ives, Cambridgeshire. An agenda and registration form will be sent out shortly.

To book a place or for further information, please contact Poly at PharMIG on 01992 478675 or poly@pharmig.org.uk

editors note

Dear Reader, my last note to you was in a more serious vein than I intended for the editors note. There is enough heavy stuff in this business without me harping on, but to be honest that was how I was feeling at the time. You know how it is, the pre-inspection blues, a little paranoia knowing that you can never do enough microbiology. Suddenly you forget about the great validation work or the brilliant investigation report and only see gaps and holes where in reality everything's fine, although maybe not perfect. The post inspection euphoria (having done so well) passed a while ago and things are back to normal.

We have a heat wave. Great, as it's the start of the weekend. The only problem with this is that most laboratory HVAC's are not designed to cope with these lovely hot spells we get every few years. I understand it's something to do with cost. So in the labs we have bells ringing indicating that the odd incubator is above specification. No great problem as it's a rare occurrence and we can move things around to ensure we comply. It's strange though, that the old water jacketed incubators that date back to Pasteur work fine but the new fangled high tech ones suffer. Of course the old water-jacketed incubators are the ones you replace because they are old and don't look good in a modern lab. Don't deny it!

Enough of this waffle. I have been asked by the PharMIG Committee to tell you what is required for an article in a newsletter so that more readers can contribute – please!

Requirements for articles to be published in PharMIG News:

Rule No. 1 There are no rules. The only limiting factor is length. More than 4 pages of A4 is getting to be too long and I may suggest that the article goes on the web page or is edited but it could still be appropriate to use it in its original form. A few lines of text, a quarter of a page to four pages are fine.

What to write. This is very much up to you. If there is at least a tenuous link to Pharmaceutical Microbiology it would be advantageous but there are no rules. Articles have focused on test methods and have been fairly technical which is good but does not mean we cannot have lighter material.

Style. Pick the style to suit what you are writing. This is not a formal journal that requires everything in the 3rd person but use it if you wish.

Pictures. Yes please, the more the better. Photographs, charts and diagrams all help to make an article more interesting but are not essential. At times I will obtain or take photographs to add a little colour to an article.

Finally, please contribute as your views will make it PharMIG News.

Paul Lovegrove-Saville Email: paul@pharmig.org.uk



PharMIG Disinfectant Action Group Questionnaire

- Summary of results

PharMIG disinfectant Action Group:

Trudy Adjrah (Roche Products Ltd)
Christine Bambrook (Aventis Pharma)
Roshan Bewick (GSK R+D, Ware)
Sandra Dundas (Cantab Pharmaceuticals Ltd.)

Elaine Dymond (GSK, Packaging, Ware)
Melissa Jeggo (GSK, Harlow)
Christine Seymour (GSK, Crawley)
Kevin Shade (Bio Products Laboratory)

Introduction

We are pleased to be able to present a summary of the results of the PharMIG Disinfectant survey conducted at the end of last year.

This was the biggest survey to date conducted by a PharMIG Action Group. Thank you to everyone who responded, we wouldn't be able to make an impact if we didn't have your views. Over 400 surveys were sent out to UK Hospital QC Pharmacies, and Universities with a Pharmacy School, Pharmaceutical and Biotechnological organisations in the UK and mainland Europe. The aim was to gain an insight into disinfectant practice and implementation across the industries. The responses however, only came from the hospital pharmacies and pharmaceutical and biotech companies in the UK and Ireland.

In reality then, the survey was a reflection of practice within UK QC hospital pharmacies, and the UK pharmaceutical industry. The high level of response from the hospital pharmacies was encouraging, and hopefully marks the beginning of further collaboration between the two groups.

Due to these two main areas of response, the summary is a comparison in practice within the hospital QC pharmaceutical environment and the pharmaceutical/ biotech industry. The summary makes interesting reading, with some stark contrasts in practice within the two industries.

This year looks like being another busy year for the Group, as we have plans to collate a monograph of current disinfectant usage, and also to publish this survey data in a more formal publication, so watch this space.

Ode to *Pseudomonas* spp.

There once was a bug called
Pseud'
Who grew with only a little food,
In the water he loved to swim,
Attaching to whatever took his
whim.

UV light put in systems to keep
him away,
Doesn't have much effect he just
makes hay,
When he ends up in drugs he's a
real concern,
How to detect him we must all learn.

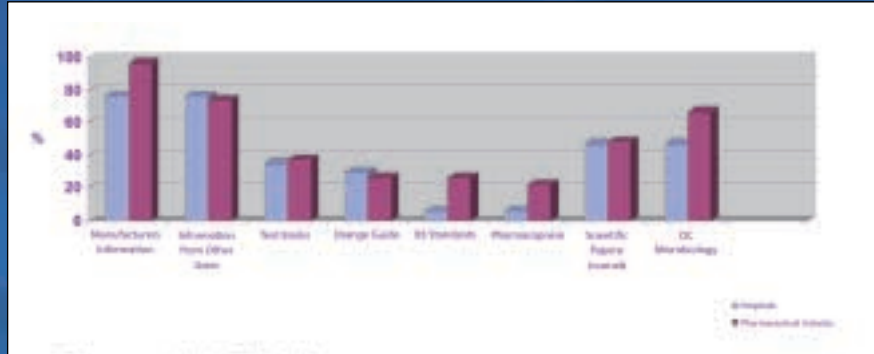
When cultured on TSA on sugar
he fed,
Not used to all the rich food he was
often dead,
If he was fed instead on R2A,
Would he still be here today??

Section 1 : General Disinfectant Policy

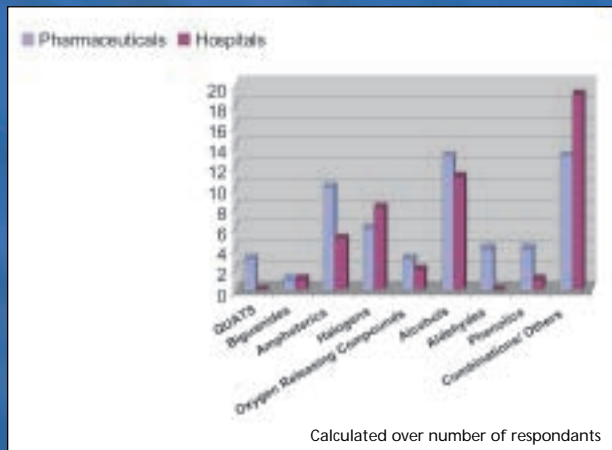
1.1 Is the quality department (either QC or QA) involved in the choice of disinfectants?

	Pharmaceutical Industry	Hospitals
Yes	96.2 %	76.4 %
No	3.7 %	23.5 %

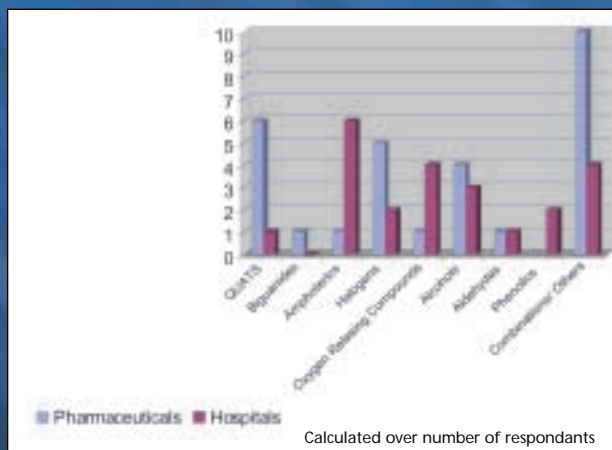
1.2 When deciding what disinfectant to use how is the information sourced?



1.3 Types of disinfectants used In sterile areas



1.4 Types of disinfectants used In non-sterile areas



1.5 For aseptic areas are disinfectants prepared in-house?

	Pharmaceutical Industry	Hospitals
Yes	66.6 %	58.8 %
No	7.4 %	41.1 %

1.6 For aseptic areas are disinfectants bought in pre-sterilised ready to use formulations?

	Pharmaceutical Industry	Hospitals
Yes	40.7 %	64.7 %
No	37.0 %	35.2 %

1.7 Are the disinfectant manufacturers audited?

	Pharmaceutical Industry	Hospitals
Yes	18.5 %	11.7 %
No	77.7 %	88.2 %

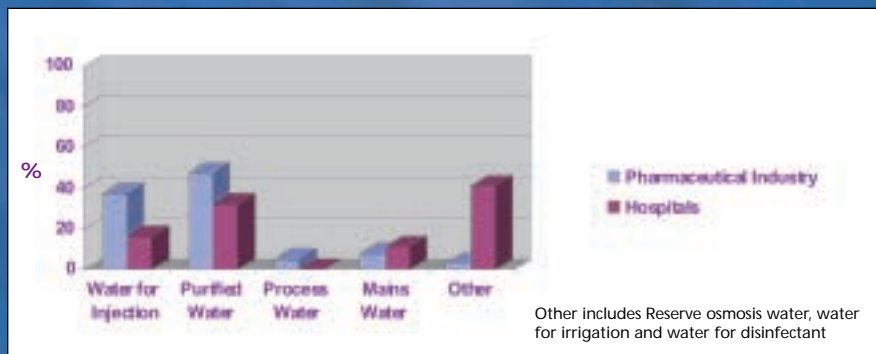
1.8 Are certificates of analysis obtained from the manufacturers?

	Pharmaceutical Industry	Hospitals
Yes	55.5 %	29.4 %
No	25.9 %	64.7 %

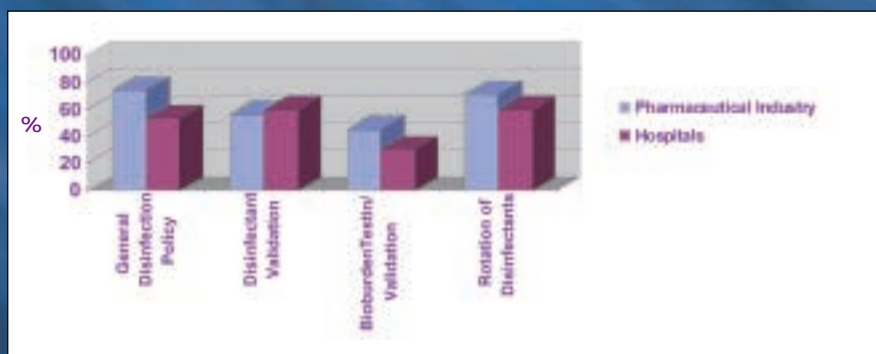
If YES, do the certificates of analysis include microbiological testing?

	Pharmaceutical Industry	Hospitals
Yes	33.3 %	80.0 %
No	53.8 %	20.0 %

1.9 What type of water is used to dilute disinfectants?



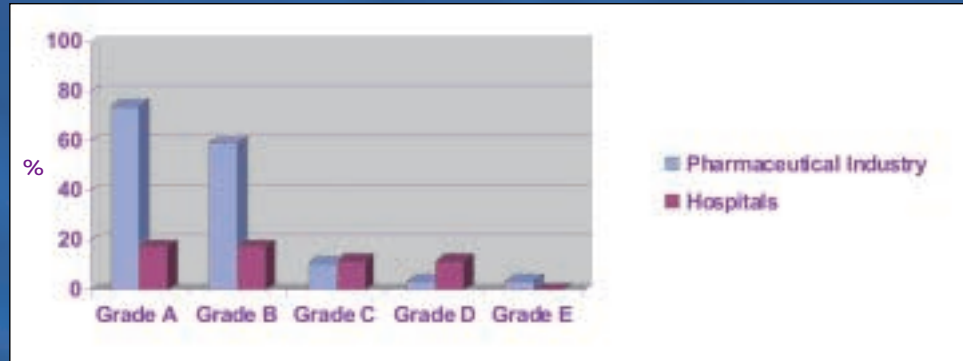
1.10 Have regulatory bodies ever put questions to you regarding any of the following:



1.11 Is formaldehyde gassing still performed?

	Pharmaceutical Industry	Hospitals
Yes	44.4 %	5.8 %
No	40.7 %	94.1 %

1.12 In which of the following grades of areas would disinfectants be filtered sterilised into?



1.13 With environmental monitoring, does the media used contain disinfectant inactivators?

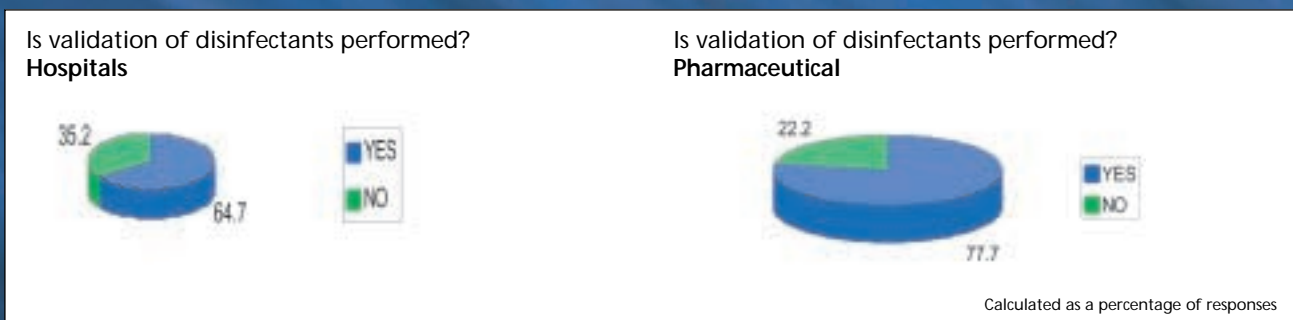
	Pharmaceutical Industry	Hospitals
Yes	74.0 %	29.4 %
No	25.9 %	70.5 %

Types of inactivators used by questionnaire participants:

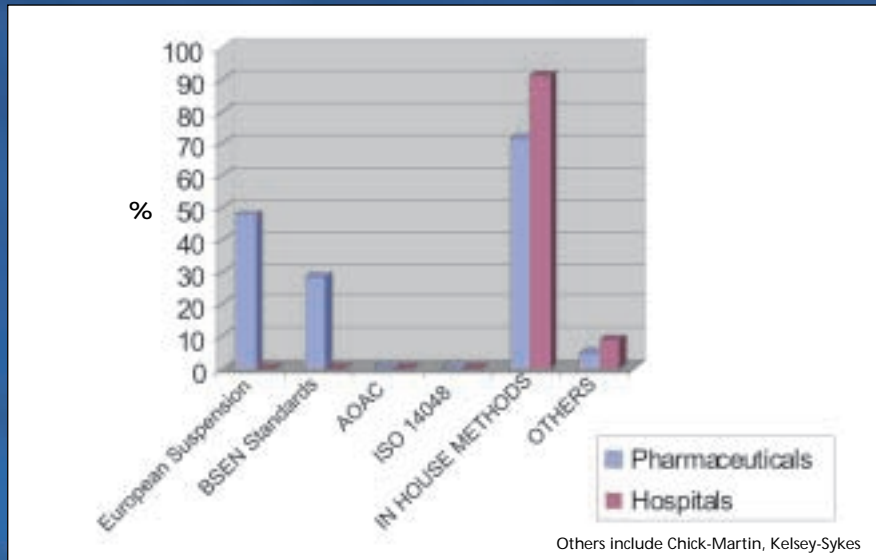
- Tween, Lecithin
- Lecithin, Tween 80, Sodium Thiosulphate, L-histidine
- Lecithin 0.7%, polysorbate 20 5g/L
- Bromocresol purple
- Oxoid 'Protect' Agar
- Biomerieux Contact plates
- Dey Engley for contact slides
- Lubrol, asdectin/ polysorbate, sodium thiosulphate
- D/E neutralising agar
- Rodac D/E plates

Section 2: Validation

2.1 Is Validation of disinfectants performed?



2.2 What test method(s) are use to validate disinfectants?

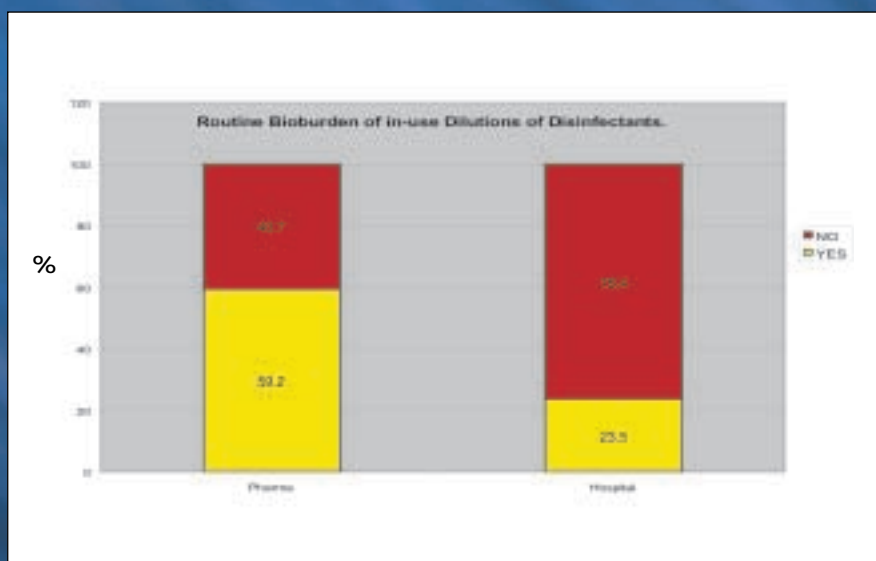


2.3 Are disinfectants periodically re-validated?

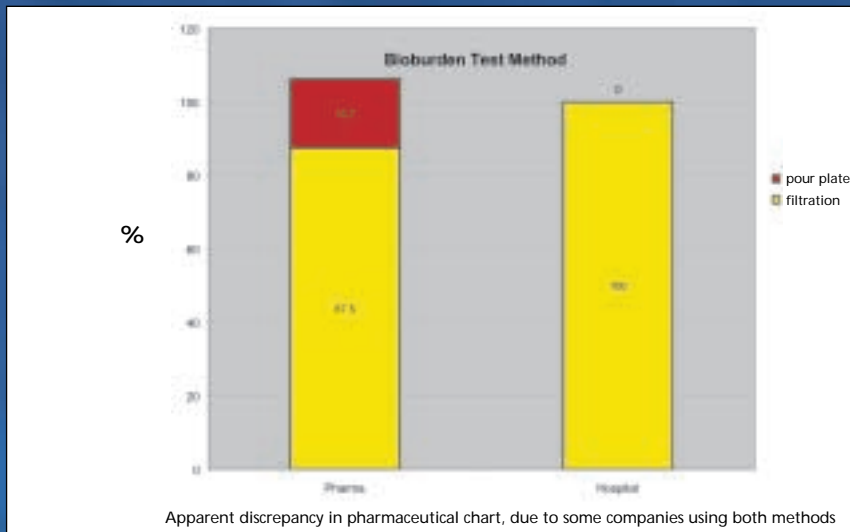


Section 3: Bioburden

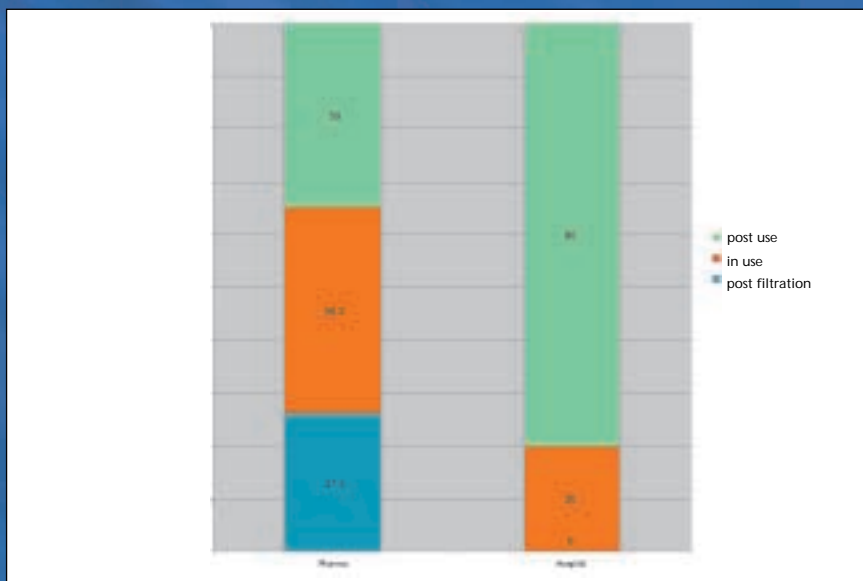
3.1 Is bioburden testing routinely carried out on in-use dilutions of disinfectants?



3.2 Which Test method is used for in-use bioburden testing?

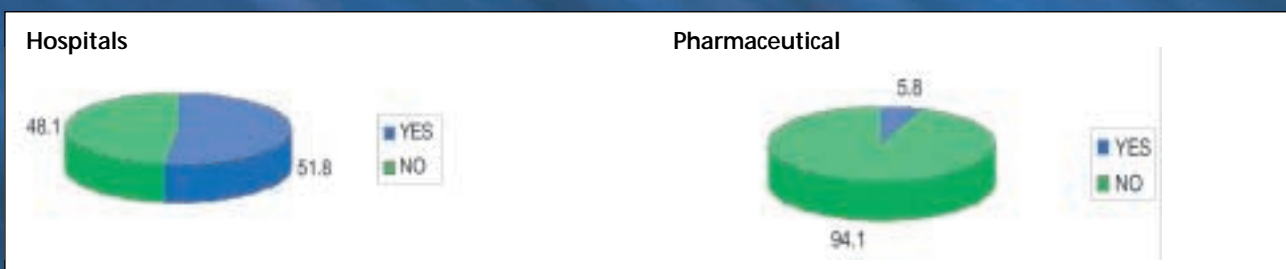


3.3 At What stage do you perform the bioburden test?



Section 4: Residues

4.1 Are disinfectants used on product contact surfaces



4.2 What method(s) are used in residue testing?

- Neutral swabs following manufacturer's specified method
- Atomic absorption
- In-house validated analytical methods
- Contact plates, swabs

4.3 What limits are set for residue testing?

- <100ug per 2.5cm² swab
- NMT 10mg / metre²
- Limit of detection
- None

4.4 What action is performed if residue testing fails?

- A re-validation is performed, product flush may be incorporated
- None immediate because equipment is already back in use. Alert relevant QP that failure has occurred. Arrange follow up test at next clean-down
- Purified water rinse
- Re-clean area, re-sanitise area. Invalidate any contact plate results
- Not applicable

4.5 How are the residues eliminated?

- Rinsing/ product flush
- Rinsing with water
- As Above (purified water rinse)
- Not applicable

4.6 Which department is responsible for residue testing?

- Analytical services (chemistry)
- QC
- Microbiological/clean-down validation lab
- Micro Lab
- Not applicable

COMMENT: Responses to these questions only came from the pharmaceutical/biotech industry. The range of responses shows the variety of work being performed in this area.

Section 5: Detergents

5.1 What detergents are used in:

- A vast range of detergents were used by both industries for sterile and non-sterile use. The included general household products to specialised formulations for the industries.

5.2 How do you know if your detergent is compatible with your disinfectant?

- Many responses from both industries either used in-house data or didn't know. Many relied on manufacturer's information.

COMMENT: Further interpretation of the data presented above will be made available at the annual Conference in November 2001. In the mean time if you have any queries you may contact any of the Action Group Members via the website or by e-mail, info@pharmig.org.uk.



**Wishing PharMIG a
Happy 10th Birthday!**

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PharMIG Training & Visits

One of PharMIG's objectives is to establish relevant training courses that would meet the academic, practical and developmental needs of microbiologists. The aim is to provide training that would be a benchmark and a known standard throughout industry and academia.

To date we have set up a successful training programme on the validation of disinfectants at the beautiful site of Bath University. We do want to sincerely thank Dr Rosamund Baird and Prof. Anthony Smith in helping us to organise this course. This course will be repeated on a regular basis, updated with current information. For those who want to attend this course you may want to check out the summary in the next newsletter.

We are now actively seeking courses and venues that will run routinely. We hope to provide a basic standard course in industrial and pharmaceutical microbiology and aseptic handling procedures for sterile and clean room suites. We ask all our Members to advise on any relevant courses. Please e-mail your ideas to me on aruna@isotron.co.uk, or Sue Wilson at sue.wilson@bcm-ltd.co.uk.

We would like to encourage Members to consider getting involved in a working Group for training. This Group would be involved in brainstorming ideas for training courses, help to find suitable sites and co-ordinate the organisation of the course. If you are interested, please contact Sue or me.

This year we decided to take a break from the regular visits to our favourite sites at the PHLS, Colindale and the IMI, Egham. We visited Steris Ltd in Oxford and Celsis Ltd in Cambridge, which were a success. We are now planning a visit to the Public Health laboratories at Liverpool and a Company visit to Eli Lilly in Speke for the New Year. If you have ideas for day visits or you are willing to host a visit, please contact us.

We can also be contacted via the website www.pharmig.org.uk.

Arun Acharjya Training Co-ordinator arun@pharmig.org.uk



**Steris would like to congratulate
PharMIG on their 10 year milestone
- here's to the next 10 years!**

Steris House, Jays Close, Vibles, Basingstoke Hants Tel: 01256 840400

Annual subscriptions

Just a reminder to everyone who has not paid their annual subscription to PharMIG for 2001, that this is now **very overdue!!** Invoices were sent out to everyone in their Members pack so please check that you have sent it on to your accounts department. May I remind you that a discount is only available for PharMIG events such as the Audit meeting and the Conference 2001, only if you are fully paid up Members.



Action Group Update from Hazel Sarosi

According to Collins English Dictionary "action n. 1. the state or process of doing something or being active...". I prefer my old faithful illustrated dictionary definition (with pictures!!!) which defines it as "exertion of energy or influence". We no longer have three very proactive Action Groups but four! The Non-sterile monitoring Action Group have had their first meeting and the minutes of this meeting are just oozing with great new ideas, an exertion of energy and enthusiasm. The objectives of the Group are very clear "To establish an industry wide guideline on non-sterile monitoring that will define what we must do, together with a rationale for why we do it". I am sure that this will influence us all in our decision making processes in the future in an area where very little is currently documented. Details of this Group are now on the Website.

As you are probably aware by now (you should have received your conference flyer – contact Poly if you haven't), this year is PharMIG's 10th Birthday. The Action Groups will be presenting their work over the last year. I hope we can count on your support there. Trudy Adjrah will be presenting on behalf of the Disinfectant Group, Lynne Arnot for the Bacterial Endotoxin Group and Natasha Gibbs for the Steam Sterilisation Group.

The Disinfectant survey results are included in this issue and give a summary of our practices across the UK in both Hospitals and Pharmaceuticals and the Group are already thinking about the content of a technical document. The Steam Sterilisation Action Group (photographed below) is making great headway with their technical document. I am becoming more excited in anticipation of seeing the final product. This would not have been possible without the help of each of you who took the time to complete the questionnaires – many thanks again. Do not think that the summary review of these documents is the end. On the contrary, it is the beginning! With this in mind, it just remains for me to say that the Bacterial Endotoxin Group questionnaire will be finding its way to your desk sometime soon, so please be sure to find some time and return it to Lynne.



Top row, left to right: Emma McNeely, GSK R&D; Hester Pearson, Boots; Judith Boothman, AstraZeneca; Lindsey Williams, Aventis; Mark Asquith, AstraZeneca;
Bottom row, left to right: Joseph Day, GSK; Natasha Gibbs, GSK R&D and Christina Oniah, Aventis.

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