

Microbiological Quality Control: Why Do We Bother?

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What is Analytical Quality Control

ISO 9000 Quality Management Systems –
Fundamentals and Vocabulary (2005)

Quality Assurance *“part of the quality management focused on providing confidence that quality requirements will be fulfilled”*

Quality Control *“part of the quality management focused on fulfilling quality requirements”*

Or alternatively ...

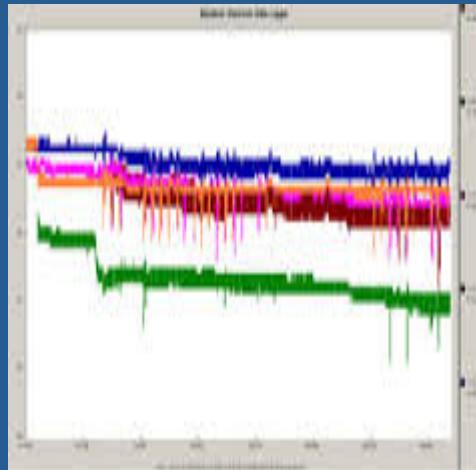
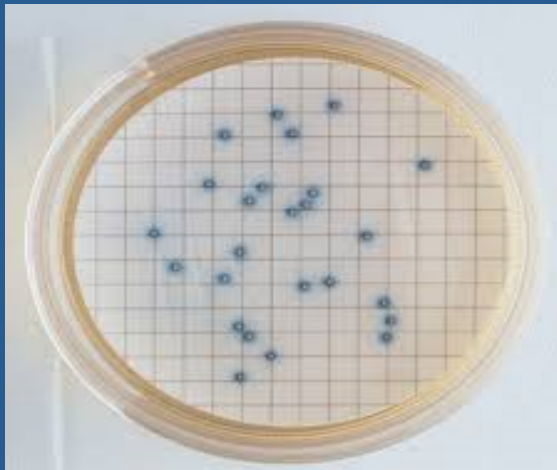
ISO 8402 – Quality Management and Quality Assurance – vocabulary (1994)

Quality Assurance *“all those planned and systematic actions necessary to provide adequate confidence that a product, process or service will satisfy given quality requirements”*

Quality control *“the operational techniques and activities that are used to fulfil requirements for quality”*

Or maybe....

Understanding all the factors that can have an impact on results of analyses



Some aspects of controlling the quality of media from media manufacturers

pH value - check that the pH of the prepared medium, when tested in final form at ambient temperature (25°C) lies within the range given on the product label. The medium should be discarded if the pH value lies outside the specified range.

Some aspects of controlling the quality of media from media manufacturers

Sterility: a representative sample of each lot/batch of medium should be incubated for 2-5 days at 35-37°C. As a general rule, for a lot of 100 or less units a 3-5% sample should be tested. For a larger lot, 10 random plates or tubes are taken. There should be no evidence of microbial growth after incubation. Discard all sterility samples when the tests have been completed.

Some aspects of controlling the quality of media from media manufacturers

Growth performance: test the growth support properties of the product by inoculating the medium with appropriate stock cultures and/or fresh isolates. Use a standard inoculation procedure and examine the quantitative and qualitative results obtained. If testing new lots/batches of media, inoculate old and new lots in one test and compare the performance of the two lots side by side.

Some aspects of controlling the quality of media from media manufacturers

Stability: periodically perform the above procedures on stored prepared media in order to determine whether the storage conditions will give optimal results.

NOTE: If a medium does not perform to expectations and all the manufacturer's recommendations have been followed, then the following steps should be taken:

- 1** Record the nature of the problem and the method of preparation of the medium.
- 2** Note the lot/batch number and the date it was received.
- 3** Call the Technical Support department of the company.

Manufacturers or Professional Bodies?

Manufacturer: “If testing new lots/batches of media, inoculate old and new lots in one test and compare the performance of the two lots side by side”

Australian Society for Microbiology: “Comparison with a previous lot/batch should be discouraged because of the possibility of insidious decline of performance standards”

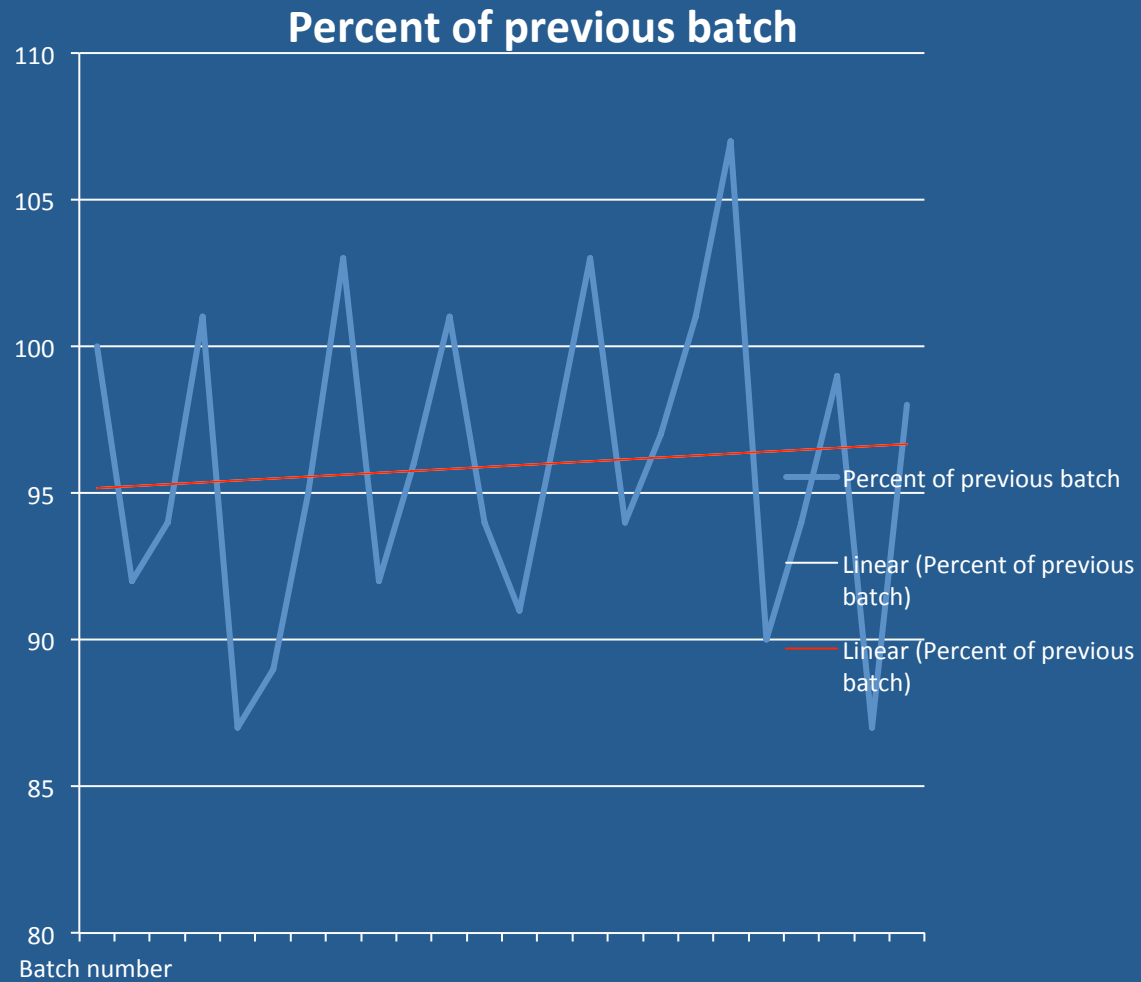
Helpful isn't it!!!

A real world example

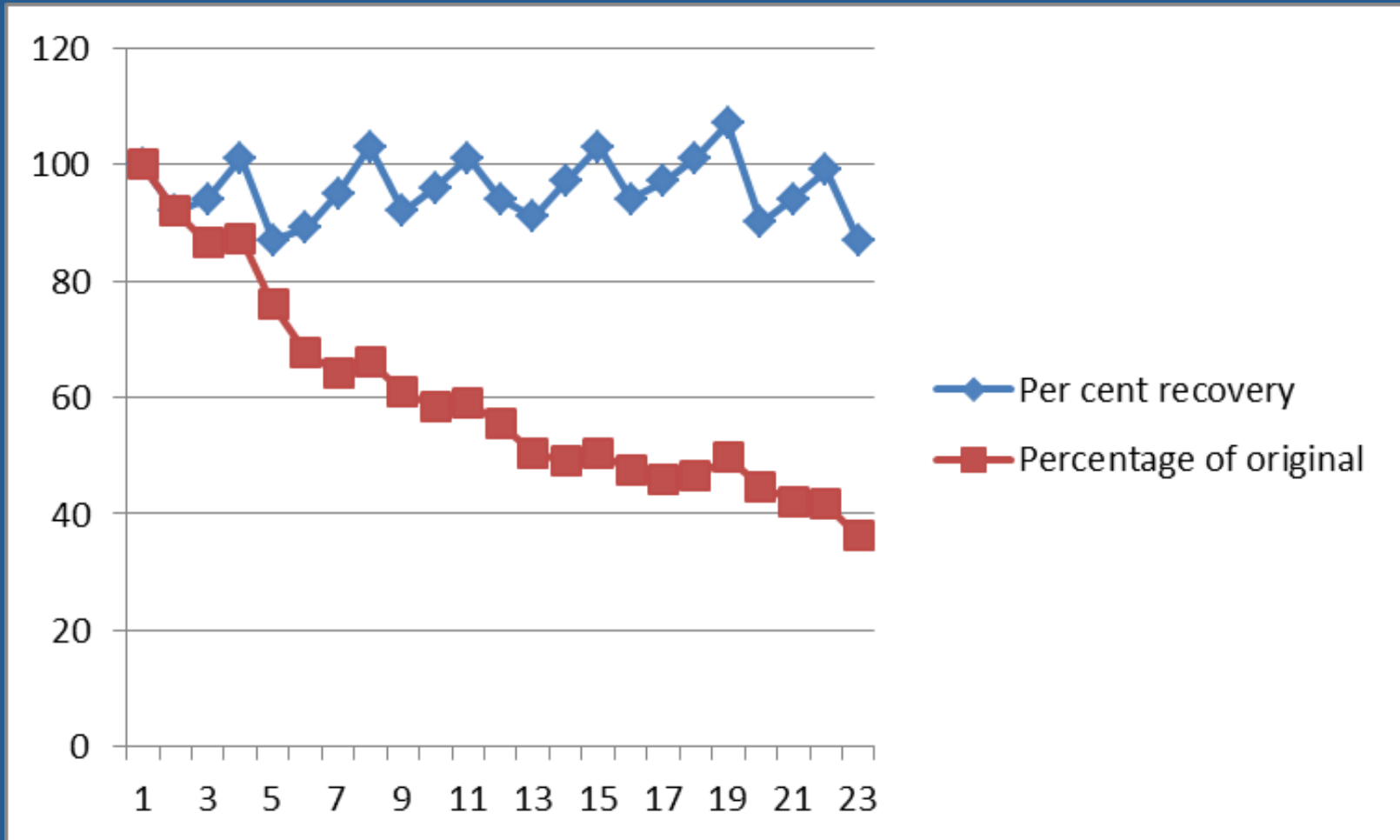
A laboratory's quality control procedure stated "When preparing a new batch of medium, the performance must be tested against the previous batch. If the recovery of *Legionella* on the new batch is not within 85% of the previous batch then the batch should be discarded.

Very commendable and accepted by the accrediting body.

These are the results



But this was the effect!!!



And the moral to that story....

If you compare the recovery of new batches of media to that of a previous batch you MUST use a chart showing the overall performance

Alternatively compare to a non-selective medium and determine percentage recovery

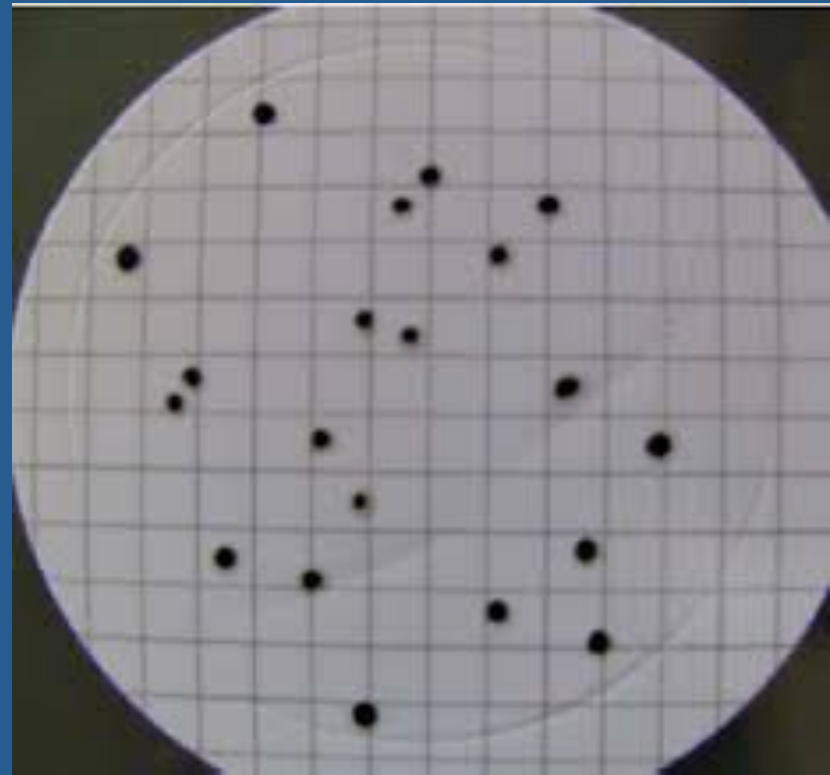
Or better still compare to a non-selective medium with a known number of target organisms

Control of media performance

Like this?



Or like this?



Qualitative or Quantitative control?

- Many labs use qualitative QC for control of media performance
- This can give an insight into factors such as colonial morphology but does little to assess recovery
- Heavy inocula can give a false impression of medium performance
- Quantitative QC leads to a better understanding of overall performance

What do the chemists do?

- A presence/absence control is meaningless
- Chemists typically run a low and high control
- Results have to be within an acceptable range
- Results are plotted to demonstrate ongoing performance
- Chemical quantitative control is easy due to the high number of ions/molecules present
- 1 ppb is still millions of ions/molecules!!

Quantitation in microbiology

- Requires low numbers of target organisms
- 0 – 300 for 90 mm Petri dishes, 0 – 80 for membranes
- The real area of interest is 0 – 30 cfu
- Difficult to generate suspensions reliably
- Fortunately reference materials are commercially available (Bioballs, lenticules etc)

Quantitative QC in action

The performance of media was studied using qualitative and quantitative QC

Media was “adulterated” intentionally by overheating, dehydration, incorrect concentration, lengthy storage and incorrect incubation temperature

QC procedures were adopted from two reputable laboratories

Quantitative and Qualitative QC

	Qualitative QC		Quantitative QC	
	Growth	Appearance	Growth (cfu)	Appearance
"Good" media	+++	OK	28	OK
Overheated	+++	OK	21	OK
Dehydrated	+++	OK	25	OK
Long storage	+++	OK	19	OK
High temperature	+++	OK	16	OK

E. coli with Bioballs

	TSA	Colilert	mFC
"Good" media	6	6	6
Overheated	5	NA	4
Dehydrated	6	NA	5
Long storage	4	6	2
High temperature	6	7	0

“Ideal” QC

- Quantitative procedures essential
- Low level inocula (5-30)
- Use both the medium of interest and a non-selective medium
- Set realistic targets for acceptability
- Analyze the data appropriately
- Look at the data before reporting results!!

Summary

- Quantitative QC highlights issues that qualitative fails to detect
- The use of qualitative QC procedures overestimates performance
- Quantitative QC is more expensive but worth the money!!
- Let's put more science into the science of microbiology!!!