Spotlight
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SPOTLIGHT

Electronic Management of EM Results in the Microbiology Lab

Critical Considerations & Financial Justification

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Microbial EM Programs & Data Management

An appropriate microbiological environmental monitoring (EM) program should be established and used in production and laboratory facilities for both sterile and non-sterile products (1). The most stringent application of these procedures is for sterile products manufactured by aseptic processing.

"In aseptic processing, one of the most important laboratory controls is the EM program. This program provides meaningful information on the quality of the aseptic processing environment (e.g., when a given batch is being manufactured) as well as environmental trends of ancillary clean areas. Environmental monitoring should promptly identify potential routes of contamination, allowing for implementation of corrections before product contamination occurs (211.42 and 211.113)" - FDA Guidance for industry (2).

Documents, such as the PDA TR13 (3), and articles (4, 5) identify microbiological control concepts and principles as they relate to the manufacture of sterile pharmaceutical products, and these concepts can also be applied to non-sterile product manufacture. The PDA TR13 document was compiled to aid in setting up a program that is meaningful, manageable, and defendable. Many solid dosage pharmaceutical companies perform a microbial EM program periodically, and some papers provide guidance when it comes to EM of non-aseptic operations (6).

Typical pharmaceutical and biotech facilities may have several hundred or thousand environmental samples collected and processed on a daily basis. Most microbial EM programs generate a voluminous amount of data and require a large amount of time from the microbiology control labs. Due to the large amount of data that must be maintained, reviewed, and reported on, companies may consider acquiring data storage and management systems. This Spotlight addresses the critical points to look at when considering the implementation of a paperless EM data management solution.

Keywords

Environmental monitoring program, data management, paperless system, financial justification

2. Potential benefits of electronic data management systems

Today's pharmaceutical industry is facing many challenges: generic competition, cautious regulators, and cost-conscious consumers to name a few. To stay competitive, companies have to streamline their development and manufacturing processes with improved operations efficiency, flexibility, and quality control. An effective microbial EM program is critical to such successful outcomes, and using electronic management of EM results can support this goal.

Main potential benefits of an electronic management of EM results are:

- Increase operations efficiency & productivity
  - Standardized, systematic approach
  - Reduce cycle time
  - Effective tool for investigations, root cause analysis, and quicker corrective actions
  - Reduce administrative tasks and errors, freeing QC lab teams to focus on science-related topics and goals
- Insure compliance with (more and more) regulations, and readiness for inspections
- Allow immediate access and review
- Allow real-time reporting
- Archived and easy to find data
- Easy transfer of reports under different formats (.xls, .pdf, etc.)
- Export of data in standard formats to LIMS and ERP solutions
  - 21 CFR Part 11 and GAMP compliance (audit-trail, etc.)
  - Secure with protected access
- Technical features
  - Facility mapping with sampling point locations
  - Trending capabilities (statistics, charts, tables)
  - Deviation management and automatic action limits and alert notification
  - Generation of reports - Possibility to filter results, easy to generate specific reports "on demand"
  - Statistics and analysis, selective
  - Planning, scheduling of sampling tasks
- User-friendly interface (regular input of sampling results, access, navigation)
- Bar-coding capabilities to streamline data entry
- Financial considerations
  - Data system cost (purchase, yearly fees, maintenance)
  - Validation cost (and time)
- Management of new versions and updates

3. Critical considerations for an electronic EM data management system

The critical considerations when looking at implementing an electronic management system are listed as follows:

- Compliance and security

It is strongly recommended that the end-users confirm their needs in a specific document called User Requirement Specifications (URS). It defines precisely and clearly what the users expect the system to do. The document contains information about the operating environment, the required data for processing, and the functionality that the system should carry out. Additionally, the URS can contain non-process-related topics, such as processing time requirements, cost, etc.

4. Financial justification

In addition to a complete analysis detailing the clear technical benefits of an electronic management system, QC lab managers will need to build their financial case for it. It is an important task, as a return on investment evaluation will give management the concrete numbers it needs to review the value the data management system will deliver to the company and justify the investment. Some guidance to go through this process for an electronic data management system is provided below.

4.1. Financial analysis framework

The business case can be developed by listing and comparing the costs of using a manual method with the use of the new system, in situations met by the microbiology QC lab.

The cost of manual methods is mainly related to labor hours. The new data system will streamline the work and allow potential significant labor time savings. Labor hours will be transformed into $ amounts by multiplying them with the hourly rate. In the calculations, the costs related to the purchase of the new system and its implementation (= Investment), as well as its iterative yearly expenses, will have to be included.

A framework for the cost comparison with the iterative costs is represented in the table below.

As an example, the table has been established for 2 periods of 1 year, but you can decide to calculate the financial ratios over a shorter or longer period of time (depending on the company policy for such a product).

The first step in the process is to list all labor activities and their corresponding hours related to the EM program (table top part):

- when performed manually (column #3)
- when performed using the data system if purchased (column #4); this can be estimated reviewing your situation with the suppliers you consider.

The second step is to list all costs related to the EM program (table bottom part):

- when performed manually, it is mainly labor time, so a simple multiplication of labor hrs by the hourly rate (R) will give this number (M1). If there are no other iterative expenses, you simply put zeros in the following column boxes.
- for the data system, the same calculation related to labor needs to be done (S1). In addition, all specific iterative costs need to be listed (yearly license, training, etc.); review with the suppliers to establish this list.

Then, just add for each column and get the totals (T): M1T and S1T. Do the same process for year 2, and get M2T and S2T.

(1) Labor hours, (2) list to check with suppliers		Year 1		Year 2	
		Manual	eData system	Manual	eData system
Labor Activities listing (Hours)	Lab activities[1]				
	Investigations[1]				
	Inspections[1]				
	Annual report[1]				
	Total Hours				
Costs listing (Money)	Total: Hrs x R	**M1**	**S1**	**M2**	**S2**
	Yearly license[2]	0		0	
	Yearly training[2]	0		0	
	Yearly maintenance[2]	0		0	
	Total iterative costs	**M1T**	**S1T**	**M2T**	**S2T**

When the table has been completed, you can calculate the **savings** that the data system may deliver:

$$\textbf{Savings} = \sum_{n=1}^{T} \text{Costs}_M - \sum_{n=1}^{T} \text{Costs}_S$$

Where T is the period of time of your choice.

In the example over a 2 year period, it is : Savings = (M1T + M2T) – (S1T + S2T).

The **Total investment costs** (I):

I = 1) Capital investment + 2) Validation cost

It must be noted that, if the data management system allows for others benefits that will reduce the costs of the EM program, they will need to be estimated in $ and then added to the savings amount.

4.2. Financial analysis ratios

After having documented, listed, and summed all costs, it is necessary to calculate the financial ratios and value any positive return on the investment of the new data management system. Two ratios can be used: ROI, PP, as described below.

Return on Investment (ROI)

The ROI measures the overall net profit made on an investment expressed as a percentage of the amount invested. The basic Return on Investment can be calculated by dividing the company's **Net profit** (= Total savings – Total Investment) by the Total investment, and multiplying by 100 to arrive at a percentage.

The ROI for the electronic data management system is expressed below (M is Manual method, S is Data management System, and I are the total investment costs).

If the period of time is 2 years as in our example, the calculation is indicated below.

A ROI ratio greater than 0% means the investment returns more than it cost. The higher the number, the greater the ROI is.

Payback Period (PP)

In this approach, the original cash outlay (I) is divided by the annual cash proceeds (savings) produced by that investment. The PP is sometimes referred to as "break-even analysis". Measurements is in terms of years and months (months if less than 1 year).

The PP for the electronic data management system is expressed below (also in our ex.).

Financial Ratios

$$\textbf{ROI} = \frac{(\sum \text{Costs}_M - \sum \text{Costs}_S)_{\text{over period of time}} - \text{Total Investment}}{\text{Total Investment}} \times 100$$

$$\textbf{PP} = \frac{\text{Total Investment}}{\text{Annual Savings}}$$

Financial Ratios in our example:

$$\textbf{ROI} = \frac{[(M1T+M2T) - (S1T+S2T)] - I}{I} \times 100$$

$$\textbf{PP} = \frac{I}{M1T - S1T}$$

Conclusion

Electronic EM data management systems enable an EM program to become a (close to) paperless operation. Improvements in productivity and compliance enable QC teams to focus on high value science-based activity rather than administrative paperwork. And ultimately this supports company's manufacturing operations efficiency and productivity improvement actions.

Resources & References

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