

# From sample submission to tracking and trending the microflora in your production facility



**Dr Ulrich Herber**

Global Product Specialist Manager, Microbial Solutions, Charles River

Tracking and trending (T&T) is a source for vital information of the manufacturing area, so how does an IT application make an operational impact on the environmental monitoring programme (EM programme)? Highly regulated industries are required to establish comprehensive and reliable quality systems that measure the state of control of their manufacturing facility through detection, quantification and identification of microorganisms. Only Charles River offers an IT solution provided within our Customer Web Portal at no additional cost that enables the Quality Control department ability to Track & Trend the recovered isolates from their facility. The key benefits of the Accugenix® T&T tool are features that provide customers with the visibility and status not only of their samples being processed but enables surveillance of their production facility to monitor the state of control and insure their data integrity.

It is important to emphasise that our web portal and T&T application – first launched in 2012 – is available through our secured IT network and has bank level data encryption for protection. Each site has their own unique account login and password. Facility site managers and administrators can assign different levels of authority to their staff, from sample submissions to creating reports and defining the nomenclature to identify sources, sampling, products, etc. The power of this version is the customisation features for data entry fields and the ability to apply distinct filter sets, to report out the metrics and trends needed at any time.

For example, we have added input fields to assign whether the isolate was recovered from water, air, personnel or surface, as well as providing collection mode and location data, and number of colony-forming units on the plate. The data management systems allows the onsite administrator/manager to customise these input fields using their

own nomenclature to describe the relevant information about their isolates to segment and filter the data producing the reports they need.

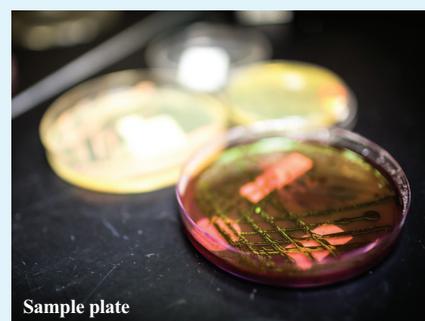
This insures standardised labelling within the site, eliminates redundancies and transcriptional errors and saves time over manual data entry into any other program supporting their EM programme.

There are several benefits of having a customisation tool for the plant management. Managing microbial risk depends on having a clear picture, to make the production environment visible. The ability to readily visualise, sort and trend identification data by their source, type and location, and collection date and time, provides a clear solution to proactively monitor the state of control of your production facility. These attributes improve the site's ability to biomap the microflora recovered and provided EM surveillance capabilities. Being able to visibly track the entire facility is a critical asset when an event leads to an investigation which requires determination of a potential source or root cause of contamination.

Our goal is to provide an integrated IT application that simplifies laboratory quality control processes by streamlining data and going beyond the standard reporting out an identification.

## Impact of relevancy and library database coverage

Superior performance, reliability and relevancy of microbial identification systems require libraries that exhibit both the breadth and depth of coverage of isolates that are relevant to the sterile and nonsterile manufacturing industries. In order to correctly identify a large percentage of the unknown isolates in manufacturing environments, the library must contain entries for the organisms most likely to be encountered. Our validated, cGMP-compliant libraries contain more than twice the number of



Sample plate

relevant species than any available library supporting commercial phenotypic, proteotypic or genotypic identification systems.

The T&T tool eliminates redundancies and transcriptional errors and saves time over manual data entry into Excel or LIMS type systems for EM programmes. Every identification of an unknown isolate is immediately added to the client's database. With 24/7 web portal availability, trending reports can be performed more frequently to ensure and maintain the state of control. Using our standard reports and applying searchable filters allows visible examination, reporting on frequency of occurrence of organisms, detection of changes within the facilities' microflora, reports based on Gram reaction, specific morphologies and spore formers. With a click, one can produce a report showing the objectionable organism list that the site has customised or observe changes based on seasonality. Administrative users, with multisite responsibility, can easily trend common raw materials that might be used at several production sites. The key benefit for compliance is that the data is available and instantly accessible to produce accurate reports for immediate evaluation to visibility manage and control any risk. 

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