Efficiency Management in Quality Operation
cME & Smart-QC Newsletter

Dear Colleague,

Welcome to cResults Newsletter, designed to offer you insights, news, information about Quality Operation Efficiency Management, Software solution: cME (www.cmanageefficiency.com) to manage batch record release and overall QA efficiency, Smart-QC (www.smart-qc.com) for QC Laboratories Planning and Scheduling, events and quality related efficiency improvement ideas.

We hope this issue of cResults Newsletter will spark new ideas to help you better manage your quality operation, and improve your customer service level. At the end of the day, we are not successful unless you are.

Sincerely,
Rafi Maslaton *President, cResults*
Please be sure to register for our upcoming Webinars: Documentation Errors Reduction Methodology and Overall QA Efficiency, KPI in Quality Operation and Resource Planning, Scheduling and COQ for QC Labs.
This Newsletter is dedicated to **Cost Allocation – How to allocate in-direct and over-head cost to each product**

QA: Our industry has transformed into Lean and is paying more attention to cost and data. It has become apparent that our platform to assess cost in the Quality Operation is relatively antiquated and inadequate to address many of the challenges of today's business environment. We are asked to improve our cost accuracy to better analyze cost reduction opportunities and address items such as:
1. Make or buy decisions
2. Products rationalization *(which products should be stopped, or outsourced and the quality cost may play a major role in some of these decision)*
3. Automation projects, Information Systems ROI

Cost per sample Example using cost drivers, accurate STD and integrated cost model with forecast and capacity planning

Let's begin our journey in exploring the approach needed and the model to better allocate cost in the Quality Operation to improve the accuracy and to provide better information to address some of today's challenges. The 1st step in any accurate costing effort is to establish accurate standards for both staffing and equipment. These include accurate quantification of the Hands On Time (HOT), the direct cost to perform a test, to review a batch record, to perform an audit, to conduct an investigation, OOS and more. Standards for the equipment used in the process are also needed (mainly for the QC labs). The standards are used to better allocate the other indirect and overhead costs such as Calibration, Engineering Support, Validation, Management, Depreciation, HR, Security, Maintenance and more. The need for an allocation cost methodology is due to the fact that collecting data for each of the in-direct and OH cost items and associate these to the product level may require a major effort and in some cases it may not be feasible. When we are using allocation methodology, the more accurate standards and allocation method the more accurate we can get to the product specific cost. For example, for Calibration Cost, allocation method could use the actual equipment run by a specific product relative to the other products using its standard for run time. If Product-A uses HPLC 20% more than Product-B, then the cost allocated to product-A will be set accordingly. Then, the allocated cost will be divided into the total number of batches produced to get the allocated cost of calibration to Product-X. This brings another element to our cost allocation model which is cost drivers. These help define how to allocate the cost to each individual product. Cost driver can be volume, direct hours (Hands On Time), equipment hrs., lab square feet etc. Once we determine what are the cost drivers, we can use the specific standards / cost drivers to allocate cost to individual products.

In QA, we can use the approach by developing standards for batch record review, investigation, audit and allocate these on the products specifically based on their usage. The above are simple examples for cost allocation and we obviously need to develop the cost drivers, allocation method for each of the cost categories, and use the drivers and standards to more accurately allocate the cost.

Cost Drivers Example

Parameter ID	Parameter Description	Comments
100	Volume (Samples)	Allocation will be done based on number of Samples in the applicable work center
200	Square Feet	Depreciation will be allocated based on actual space used by each work center
300	Hand On Time (HOT) ANALYSTS	Allocation based on HOT used in each applicable workcenter
400	Instrument Time (Equipment Hrs.)	Cost as Calibration, Engineering will be allocated based on Instrument Hrs. as a mea...

Upcoming Events:
- February 13th on **Planning and Scheduling in QC Laboratories www.smart-qc.com.**
- February 20th on **KPI In Quality Operation.**
- February 27th 2009 on **Batch Record Documentation Errors Reduction Methodology & QA Efficiency.**
Please visit our web site **www.cmanageefficiency.com**, **www.cresultsconsulting.com**, **and www.smart-qc.com** for the latest events