IFMR GRADUATE OF SCHOOL OF BUSINESS

Working Paper WP21-012

VERSION NO.1

[03/21]

A TECHNICAL NOTE ON ACTIVITY BASED COSTING FOR PHARMACEUTICAL MANUFACTURING

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Abstract

Pharmaceutical manufacturing is divided into two major stages: the production of the active ingredient or drug (primary processing) and secondary processing, the conversion of the active drugs into products suitable for administration. This article deals with designing an ABC model for formulations manufacturing (the synthesis of the active ingredients and their usage in drug formulations to deliver the prescribed dosage.) The article outlines the steps involved in designing an Activity based costing model in a tablet manufacturing scenario, its relevance and the keys to sustaining the same

KEY WORDS

Activity based costing, cost model, resource drivers, activity drivers, Value added and non value added activities, formulations, unit operations

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A TECHNICAL NOTE ON ACTIVITY BASED COSTING FOR PHARMACEUTICAL MANUFACTURING

Introduction

Pharmaceutical manufacturing is divided into two major stages: the production of the active ingredient or drug (primary processing) and secondary processing, the conversion of the active drugs into products suitable for administration. This article deals with designing an ABC model for formulations manufacturing (the synthesis of the active ingredients and their usage in drug formulations to deliver the prescribed dosage)

For a pharmaceutical company, one of the prime objectives is to comply with the processes set forth in the Standard Operating Procedures (SOPs) to ensure compliance reporting with FDA. In many cases, the focus is to stay compliant while losing sight of key indicators that drive profitability and organizational goals.

In continuous production and batch manufacturing processes which are the hallmark of pharma formulations manufacturing, the multitude of activities involved brings about a need for costing, which ties to each activity. There are always many moving parts in identifying the right cost breakdown structure. When there is a need to provide key analytics for stakeholder reporting, it is imperative to measure true costs. It is in this context that Activity based costing model gains importance.

2. Brief of ABC

Activity Based Costing (ABC) is a method of measuring the cost and performance of activities and cost objects. It assigns costs to activities based on their use of resources and assigns costs to cost objects (products with route and customers) based on their use of activities. The Key point is *ABC recognizes the causal relationship between cost drivers and activities*

ABC uses multiple resource and activity drivers to improve the causal relationship between cost object and the costs incurred.

2.1 The cost assignment view

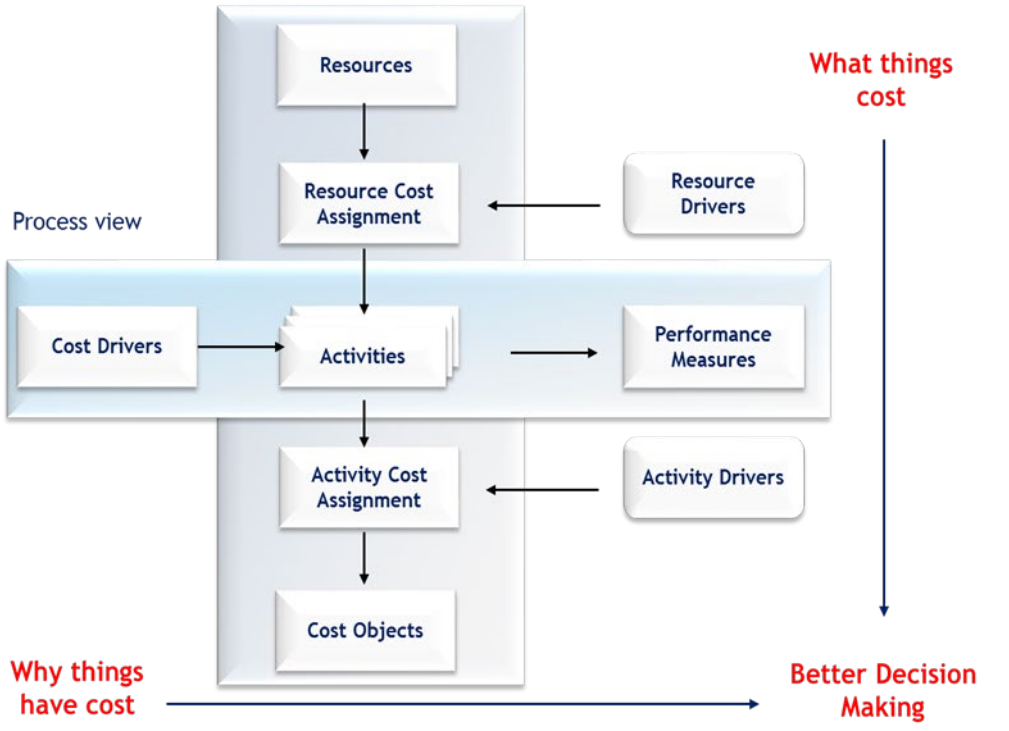
The vertical view represents ability of ABC to report more accurate product and customer related costs. This view represents the cost measurement aspect of a costing system. Resources are consumed by activities and activities are demanded by cost object. The costs of resources are assigned to activities through resource drivers and costs of activities are assigned to cost objects through activity drivers**.**

2.2 The Process view

The process view of ABC provides information about activities including the resources required for performance of activities, the cost of activities, distinction between Value and Non value added activities. Performance measurements are defined to identify how well an activity is performed. The key terms in Process view are Cost Driver and Performance measure.

(Note: please refer annexure at end for definition of key terms - source Common cents by Peter BB Turney)

Exhibit 1



Ref: Glossary of Activity Based Management, edited by Norm Raffish and Peter B.B. Turney,(Arlington: CAM-I 1991)

2.3 Relevance of ABC in pharmaceutical manufacturing environment

ABC information is relevant to a wide array of business decisions in pharmaceutical organizations. It's useful for strategic decisions on pricing and product and market mix as also for operational decisions that need process-based cost information. A few of the key factors that contribute to the relevance of ABC in Pharma manufacturing are

a. Production Overheads (OH) are high in relation to Direct costs
b. Diversity in product range and number of batches and batch size
c. Products tend to use very different amounts of Overhead resources
d. Consumption of OH resources is not primarily driven by volume. Significant presence of batch & product level activities
e. Presence of significant capacity under utilization

2.4 Prior literature on ABC in Pharma sector

Prior literature while abundant in the area of Activity based costing systems is negligible when it comes to cost management systems implementation in pharmaceutical sector.

A survey of literature revealed only a couple of attempts at designing an ABC system in Pharma industry globally and even that was restricted to limited purpose. The first attempt was by Kaplan and Team at Teva Pharmaceuticals Limited to enable it to fix its transfer prices post entry into the generics market. (Robert S.Kaplan, Dan Weiss, and Eyal Desheh. "Transfer Pricing with ABC." Management Accounting, Institute of Management Accountants (May 1997): 20–28)

The other major work was an attempt at implementing an ABC system in a drug discovery environment. "Design and implementation of an activity-based costing system in a pharmaceutical drug discovery environment", by **(**Bernard Coulie, Ntheadine De Decker, Vic Maes & Filip Roodhooft - https://onlinelibrary.wiley.com/doi/abs/10.1002/ddr.20088)

It is this context (Lack of literature on Costing implementation in Pharma sector) that this paper on ways and means of implementing a full-fledged ABC system and the key to sustaining the same becomes relevant

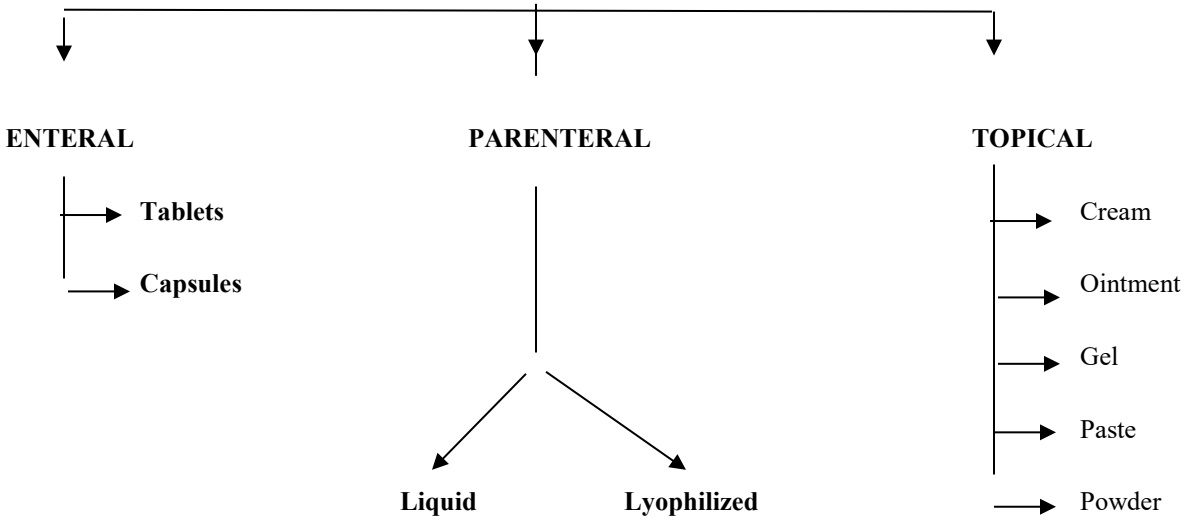
In this article we are highlighting the steps involved in rolling out an ABC system for a formulation manufacturing unit and also the keys to sustaining the same in the long run.

3. Formulation types, tablets and tablet manufacturing Process

Formulations manufacturing involves the synthesis of the active ingredients and their usage in drug formulations to deliver the prescribed dosage. Formulation is also referred to as galenical production

Exhibit 2

FORMULATION TYPES – classification based on route of administration



(vials, IV bags, ampoules, cartridges, and prefilled syringes)

3.1 Tablets

Tablets are solid dosage forms consisting of active ingredient(s) and suitable pharmaceutical excipients. They may vary in size, shape, weight, hardness, thickness, disintegration and dissolution characteristics, and in other aspects. They may be classified, according to the method of manufacture, as compressed tablets or molded tablets.

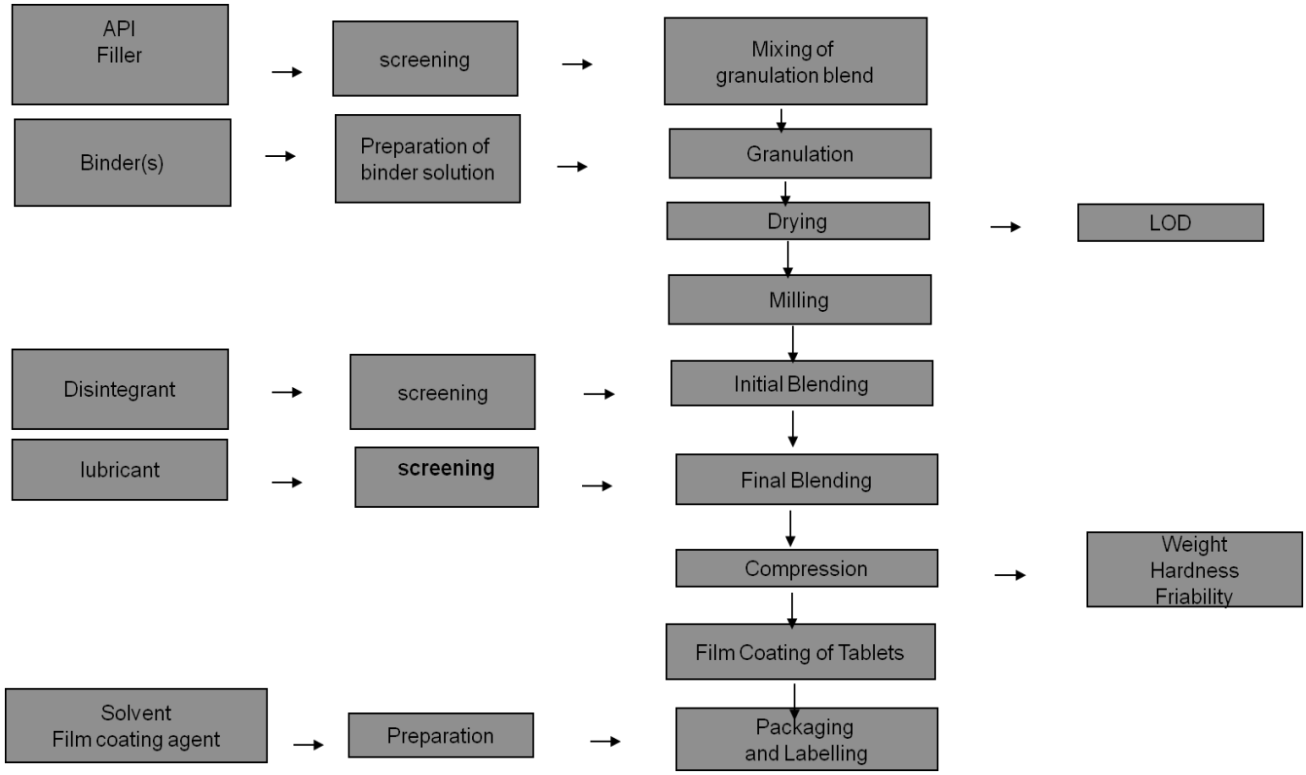
3.1.1 The Manufacturing Process - Tablets

In Tablet manufacturing every separate manufacturing step is called a “Unit Operation”. Weighing, Blending and Tabletting are individual unit operations. A “Batch” of powder or granulation is processed in each unit operation. The objective is Batch to Batch Reproducibility

in each Unit Operation. Unit Operations are determined by what manufacturing steps are needed to combine the active ingredient with other needed ingredients to make a quality finished product.

The three most common Unit Operation pathways are *Direct Compression, Wet Granulation, and Dry Granulation*. Which pathway is used depends on what is needed to make a tablet out of the active ingredient. The key to good table making is the Powders should FLOW (be fluid) and must COMPRESS (lock together) well.

Exhibit 3 - Process Flow for Tablet Manufacturing



4. Designing an ABC Model

An ABC Model is an economic map of an Organization's expenses and profitability based on its activities. Designing an ABC model is a critical stage of implementation process. It's where the structure of the system is created and *intelligence* is added. The system should provide the

right kind of information at the right level of detail. The objectives behind design of an ABC model is to provide meaningful and timely information for

1. Strategic decision making - costs and profitability of products, customers and their segments
2. Cost improvement and control - accurate costing of activities and analysis of activities into Value adding and Non-Value adding activities
3. Compliance with statutory requirements - Cost audit & transfer pricing for captive consumption & to related parties

The steps involved in creation of ABC Model are

a. Identifying activities
b. Restructuring the general ledger
c. Defining resource drivers
d. Selecting Activity drivers
e. Defining attributes

4.1 Material accounting

However, prior to targeting the Overheads through ABC, any cost model has to focus on appropriate identification of Material costs to specific batches. This requires the firm to have a robust Material accounting system comprising of Bill of Materials referred to as Master recipe in pharma manufacturing, a system for tracking of actual issues of materials to specific batches, standard I/O norms and variance analysis to break down and identify reasons for consumption patterns against standards

4.1.1 The Formula (Material cost)

The main ingredient in the formula is the Active Pharmaceutical Ingredient (API).
The other key items that go into the formula are called EXCIPIENTS
Excipients are used

a. To aid in the processing of the drug delivery system during its manufacture;
b. To protect, support, or enhance stability, bioavailability or patient acceptability;
c. To assist in product identification;
d. To enhance any other attribute of the overall safety, effectiveness, or delivery of the drug during storage or use

A few of the Key excipients are

a. Diluents
b. Binders
c. Lubricants
d. Disintegrators
e. Wetting Agents

The standard quantity required versus quantity issued per batch may be compared to arrive at Material variances.

Valuation in case of Pharma companies is based on reference to specific Lot Numbers for various items issued.

A far more complicated scenario occurs when there is a multi-tier formula where intermediates are produced and consumed into the next tier with additional flavor of substituting raw materials and continuing until the final finished product is produced. There may be times where yields are properly known before they move on to the next step and in some cases the shop floor goes by standards and records adjustments to material and operation after the final finished lot is yielded and finally closing out all tiers in the multi-tiered Master Recipe/ Formula.

It could easily become a complicated cost calculation with all tiers involved – their costs, variances and the costs being fed into the final finished product along with the final set of variances.

Table 1 - Sample Bill Of Material

TABLET - X 10 mg			
TABLET BATCH SIZE - 300000			
Tablets per strip -10			
ITEM DESCRIPTION	**UOM**	**STD_QTY**	**ISS_QTY**
FERRIC OXIDE (YELLOW)	GMS	69	69
STARCH IP (MAIZE) / MAIZE STARCH BP	KGS	9	9
MONTELUKAST SODIUM	KGS	3.12	3.17
TALC IP / PURIFIED TALC BP	KGS	1.15	1.15
COLLOIDAL SILICON DIOXIDE IP/COLLOIDAL ANHYDROUS SILICA BP	KGS	0.21	0.21
MICROCRYSTALLINE CELLULOSE IP/BP	KGS	4.2	4.2
PURIFIED WATER USP/PH. EUR	KGS	12.42	12.42
LACTOSE IP/LACTOSE MONOHYDRATE NF	KGS	22.56	22.51
FERRIC OXIDE NF (RED)	GMS	9	9
MAGNESIUM STEARATE IP/BP	KGS	0.42	0.42
CROSCARMELLOSE SODIUM NF (PRIMOLOSE)	KGS	1.68	1.68
POVIDONE IP/USP (K 30)	KGS	0.84	0.84
TITANIUM DIOXIDE IP/BP	KGS	0.09	0.09
METHYLENE CHLORIDE IP/NF	KGS	7.5	7.5
HYDROXY PROPYLMETHYLCELLULOSE IP	KGS	1	1
POLYETHYLENE GLYCOL 6000 IP/ MACROGOL BP (6000)	KGS	0.21	0.21
ISOPROPYL ALCOHOL IP/BP	KGS	11.03	11.03

PACKING BOM			
PACKING - 10 strips per box, BATCH of 60000 tablets			
CORR.BOX 690 X 510 X 255 X 7PLY E7004 180GSM	NO	2	2
TABLET X 10 TABS PRINTED FOIL 292 X 0.03MM	KGS	3.264	3.264
TABLET X 4 / 5 / 10 TABS PACKAGE INSERT	NO	600	615
CORR.BOX 335 X 245 X 235 X 3PLY E3004 180GSM	NO	7	7
TABLET X - 10 mg	**TAB**	**60000**	**60345**
TABLET X 10 TABS SHOW BOX 10 X 10'	NO	600	612
ALU .POLY PLAIN FOIL 292MM X 0.03MM	KGS	3.264	3.95

4.2 The Overhead costs & ABC Model

4.2.1 Identifying Activities (Preparing the Activity dictionary)

- The manufacture of oral solid dosage forms such as tablets is a complex multi-stage process under which the starting materials change their physical characteristics a number of times before the final dosage form is produced. Traditionally, tablets have been made by granulation, a process that imparts two primary requisites to formulate: compactibility and fluidity. Both wet granulation and dry granulation are used.

- Regardless of whether tablets are made by direct compression or granulation, the first step, dispensing, milling and mixing, is the same; subsequent steps differ.

- Numerous unit processes are involved in making tablets, including particle size reduction and sizing, blending, granulation, drying, compaction, and (frequently) coating.

a. Dispensing

Dispensing is one of the most critical steps in pharmaceutical manufacturing. In dispensing the weight of each ingredient in the mixture is determined according to dose.

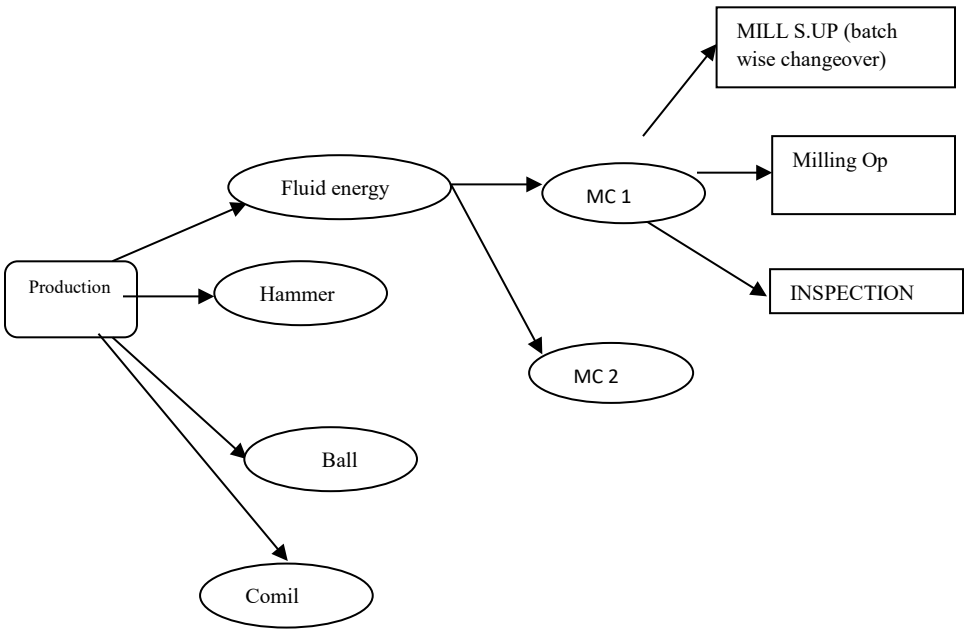
Issues like:

- weighing accuracy,
- dust control (laminar air flow booths, glove boxes), during manual handling,
- lot control of each ingredient,
- Material movement into and out of dispensary are considered during dispensing. *This is primarily a labour intensive activity and costs of this activity may be identified to different batches based on quantity of material dispensed.* The Raw Material Dispensing record is a crucial source of information for this.

b. Milling

The sizing (size reduction, milling, crushing, grinding, pulverization) is an impotent step involved in the tablet manufacturing. In manufacturing of compressed tablet, the mixing or blending of several solid ingredients of pharmaceuticals is easier and more uniform if the ingredients are approximately of same size.

Exhibit 4 - Sample Activity Hierarchy for Milling



Costs at batch level are to be estimated based on the routing adopted for that particular batch.

c. Blending

Blending is done to achieve optimum mixing of different ingredients in powder/granules at pre granulation and/or post granulation stages of tablet manufacturing.

Equipment again would be classified into

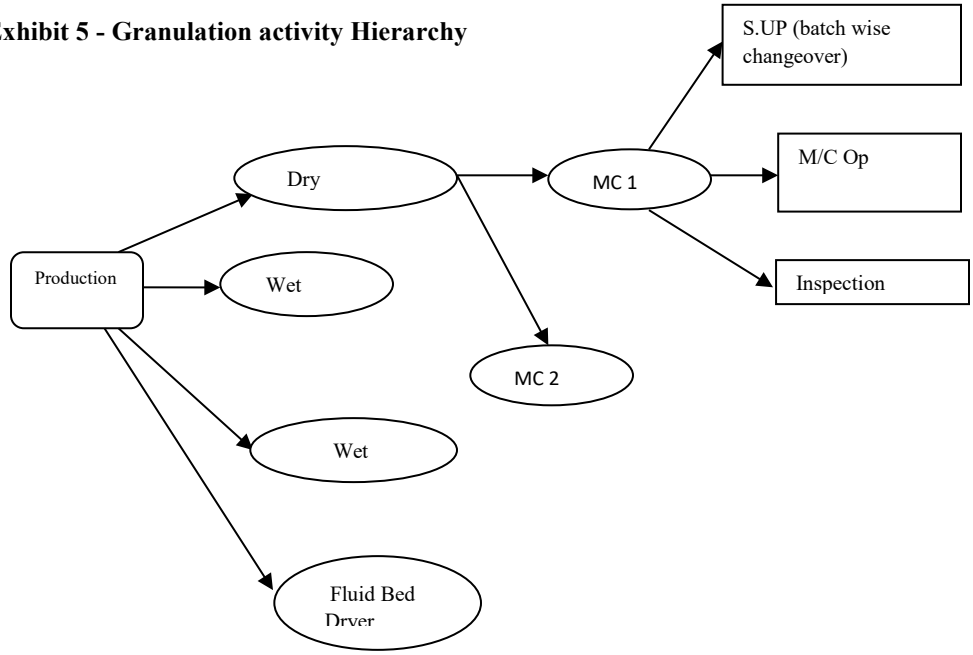
- Diffusion mixer (V, double cone, bin, drum blenders)
- Convection mixers
- Pneumatic mixers

d. Granulation

Granulation is a size enlargement process that converts small particles into physically stronger & larger agglomerates. A typical Activity hierarchy for granulation is enclosed below. Granulation is a critical operation as it provides homogeneity of drug distribution in blend and improves flow, compressibility and hardness of tablets. Again, the extent of Activity hierarchy definition would vary depending on extent of data availability in the

organizations where implemented. An associated process would be DRYING incase of Wet granulation for which a Fluid Bed Dryer is used.

Exhibit 5 - Granulation activity Hierarchy

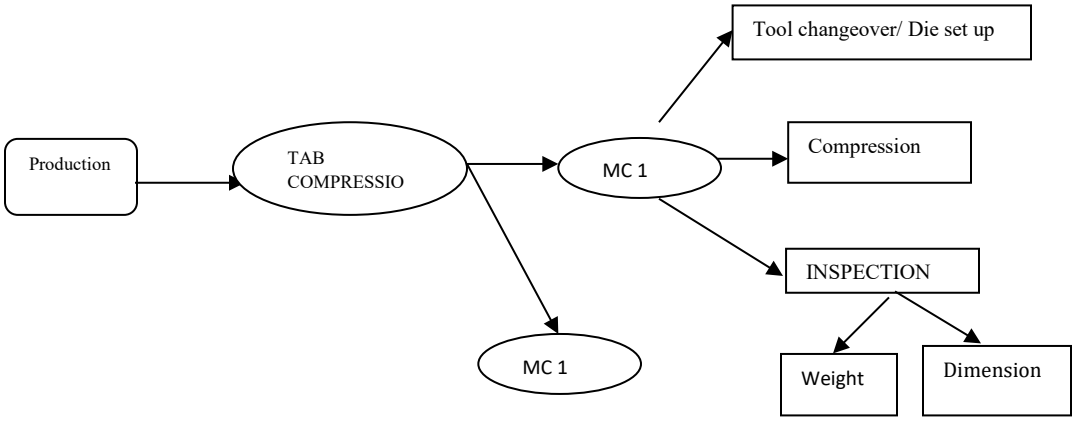


e. Tablet Compaction

- Direct Compression - It is defined as the process by which tablets are compressed directly from powder mixture of API and suitable excipients. The activities involved
  - Die Filling
  - Tablet formation
  - Tablet ejection

The primary machines used for this are ROTARY PRESSES

Exhibit 6 - A typical activity dictionary would be



In addition to equipment and manpower costs the cost of tablet tooling in the form of punches and dies is an important element of cost at this stage. The dies may be *Oval, Caplet, Round or Star* shaped based on desired tablet shape.

f. Coating

Post compression generally the tablets are coated. Coating helps in

- Making the tablet stronger/tougher
- to protect the medicinal agent against destructive exposure to air and/or humidity
- to provide special characteristics of drug release
- Improving the taste/aesthetics
- Facilitates easier handling & packing

Following type of machines are used

- Pan (standard/perforated) Coating Machines
- Fluidized Bed Coating Machines
- Spray Coating Machines
- Vacuum, Dip & Electrostatic Coating Machines

The various types of coating include

a. Sugarcoating tablets
b. Film-coating tablets
c. Enteric coating
d. Pan coating
e. Fluid-bed or air suspension coating
f. Compression coating

g. Packing

Tablets need to be packed prior to being sent out for distribution.
Blister packing is most commonly used for tablet packing. Another method is Strip packing.
Packing may be classified into

- **Primary packing material –** One that first envelops the product and holds it. This usually is the smallest unit of distribution or use and is the package which is in direct contact with the contents.
- **Secondary packaging -** It is outside the primary packaging – perhaps used to group primary packages together
- **Tertiary packaging - I**s used for bulk handling, warehouse storage and transport shipping. The most common form is a palletized unit load that packs tightly into containers.

  Primary and Secondary Packing material normally form part of the BOM (refer Packing BOM example enclosed earlier)

  In addition to Cycle time for each batch changeover time from batch to batch is a key driver of costs in packing especially Primary.

4.2.2. Restructuring the General Ledger

This involves the following steps

1. Combining related accounts (GL Codes) into Cost elements & Cost element groups. The cost element and cost element groups represent hierarchy levels of the resource expenses.
2. Decomposing expenses to department level. It needs to be ensured that all expenses (Overheads) are traced to Cost centres. The resource expenses, like salaries, wages, travel, depreciation, etc. are linked to the Cost centres in the GL Accounting System.

Wherever possible we need to ensure that expenses are directly identified to Activities/products

4.2.3. Defining Resource Drivers

Resource driver is a measure of the cost of resources used by activities. It takes the cost of resources and assigns it to activities

Table 2 - Typical resource driver for the Production activity like GRANULATION would be

	Cost Elements	Resource drivers	ACTIVITIES			
			DRY Gran	WET High	WET Low	Fluid bed dryer
Granulation(CC)	Depreciation	M/c hours (1)				
	Salaries & allowances	Man hours (1)				
	Utility	Consumption norms (2)				
	Consumables	Direct identification/m/c ours				

Note:

1. M/C hours here can indicate either the actual m/c hours or planned m/c hours for each of the machines (based on no. of batches & processing time for each of them in the appropriate m/cs
2. Utility Consumption norms are based on theoretical norms for actual production on each of the machines

Table 3 - Resource Drivers for QC function

	Cost Elements	Resource drivers	ACTIVITIES				
			Physical	NPD	Chemical	Microbiology	Line inspection
QC	Depreciation	M/c hours (1)					
	Salaries & allowances	Man hours (1)					
	Utility (HVAC)	Consumption norms					
	Consumables	Direct identification/m/c ours					

1. M/C hours here can indicate either the actual m/c hours or planned m/c hours for each of the machines (based on duration of checks – generally captured in separate QC software like LIMS)

4.2.4. Defining Activity Drivers

An Activity driver is a factor that measures activity consumption by a cost object or other activities. Carefully chosen activity drivers signal cost reduction opportunities. Activity drivers can be split into two categories

- Activity to Activity drivers (A to A)
- Activity to Product drivers (A to P)

Activity to Activity drivers - Production related

Typical example would be drivers used to drive expenses identified at Granulation (Wet High) stage to individual Granulation Work Centres (WC). The A to A drivers would be Work Centre wise Machine & Man time depending on the Cost element.

Note: Work centre related depreciation would be a direct expense (traced from Asset accounting) and consumable & tools also direct as the same can be traced to Individual WCs at the time of issue.

Typical examples of A to A drivers for Support/service functions would include

Table 4 - A to A Driver examples

Activity Description	**Receiving Activity**	**Driver Description**
STEAM GEN	Production & Service CC like QC/Maintenance	Activity wise Steam Consumption
CHILLED WATER	Production & Service CC like QC/Maintenance	Activity wise Utility Norms
BRINE	Production & Service CC like QC/Maintenance	Activity wise Utility Norms
COMPRESSED AIR	Production & Service CC like QC/Maintenance	Activity wise Air Consumption
WATER	Production & Service CC like QC/Maintenance	Activity wise Utility Norms
HR	Production & other service CCs	Activity wise No of employee
IT	Production & other service CCs	Number of Employees
QC	In process	Man & machine hours for IN PROC
	FG inspection	Man & machine hours for FG INSP
	Stability	Man & machine hours for STABILITY TESTS

Activity to Product drivers – Production related

Once expenses have been identified at Work Centre level the same would be apportioned to Batches produced in the WCs using A to P drivers like

- Batch wise Machine time
- Batch wise man time
- Set up/Change over time

The rules for Selecting Activity drivers are *(source: Common Cents – Peter B. B. Turney)*

- Pick activity drivers that match the type of activity
- Pick drivers that correlate well with the actual consumption of the activity
- Minimize the number of different drivers
- Pick drivers that encourage improved performance
- Don't pick drivers that require new measurements

4.2.5. Linking Drivers to Activities

The next step would be to attach the drivers to various activities defined. The system should be capable of enabling attachment of different drivers for each of the cost elements within an activity

4.2.6. Define Attributes

Determining attributes is the next step in developing an ABC model. Attributes are labels that enhance the meaning of the information in an ABC model. For example, an ABC model that drives process improvement can use attributes like Value added & Non-Value added to activities. This would help in identifying improvement targets. Similarly, attributes like Cost drivers and performance measures facilitate judgment on the way work is carried out and the scope for improvement. Process attributes allow a functionally organized model (which is the norm in most cases) to report activities and cost by process.

5. Keys to sustaining the ABC Model

An ABC model is a manifestation of a living organization. To represent the organization over a period of time it needs to adapt (i.e. the information it reports need to be accurate in the face of rapid changes)

a. Need to keep the model relevant when strategic and operational needs change. For example, when the emphasis is more on cost reduction there is a greater need for more detailed information on activities
b. Need to update the model for organizational changes like addition or deletion or change in production lines, process times, e.t.c
c. It is critical to cost effectively automate the regular updating of ABC data and reporting of ABC information. This might involve integrating the ABC model with transaction data sources like ERP and Quality Management systems

References:

1. Peter B.B. Turney - Common Cents, how to succeed with Activity based costing and Activity based management, (Tata McGraw Hill – 2005 Edition)
2. Robert S. Kaplan, Dan Weiss, and Eyal Desheh. "Transfer Pricing with ABC." Management Accounting, Institute of Management Accountants (May 1997): 20–28
3. Design and implementation of an activity-based costing system in a pharmaceutical drug discovery environment., Drug Development Research 67(2): February 2006, 107 – 118, 2006 Wiley-Liss, Inc.
4. David Kealing, Martin Losch Ulf Schrader– Outlook on Pharma Operations - McKinsey & Company (2010)
5. Prabir Basu, Girish Joglekar, Saket Rai, Pradeep Rai, John Vernon - Analysis of Manufacturing costs in Pharmaceutical companies, International Society for Pharmaceutical Engineering (published online on 4th March 2008 in Journal of Pharmaceutical Innovation)
6. Broekhof, Martijn, Transparency in Pharmaceutical industry – A cost accounting approach to prices of drugs, University of Groningen/UMCG Research database (2002)

Annexure I - Key definitions

1. **Resources -** Economic elements used in the performance of activities. For sake of simplicity they may be understood as expenses (example: Manpower, power, e.t.c)
2. **Activities** – Are description of work that goes on in an organization and they consume resources. Examples: Machine set up, Testing of material, production scheduling, placement of Purchase orders
3. **Cost objects** – They are the reason for performing activities. Cost objects include products, services, customers, projects and contracts.
4. **Resource drivers** – It's a measure of the cost of resource used by an activity. It takes the cost of the resource and assigns it to the activity. Example – when cost of power is assigned to machining activity based on units consumed, units consumed would be the resource driver for assignment of cost of power (Resource)
5. **Activity drivers** - A factor that measures activity consumption by a cost object. If melting is an activity performed then weight of the part would be the activity driver.
6. **Performance measure** – They define the work done in an activity and the results achieved. They tell how well an activity is performed. They include measurements of the efficiency of the activity, the time required to complete and the quality of work done.