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SPIKE

(A Solution for Pharma-Industrial Engineering
Knowledge Process Outsourcing for Enterprises)

Outsourcing IE activities for
Pharmaceutical Manufacturers



***Vrunda Consultancy
Services***

What is Outsourcing?

Outsourcing is the contracting out of a company's non-core, non-revenue producing activities to specialists.

It differs from *contracting* in that outsourcing is a strategic management tool that involves the restructuring of an organization around what it does best – its core competencies.

What SPIKE means?

- *SPIKE or A Solution for Pharma-Industrial Engineering Knowledge Process Outsourcing for Enterprises* is a kind of high value added KPO service involving Continuous Improvement & Management Support work that industry can outsource from experts where it is costly to perform
- SPIKE utilizes the *tools and techniques of INDUSTRIAL ENGINEERING with Pharmaceutical Engineering* and helps the organization to drive the efforts for achieving excellence through continuous improvement
- Services rendered may involve *low to high end quantitative and qualitative tasks*

PHARMACEUTICAL ENGINEER

AS DEFINED BY AMERICAN SOCIETY FOR PHARMACEUTICAL ENGINEERING

Pharmaceutical engineers are involved in the conception, design, construction, and operation of research facilities and manufacturing plants, where they also are involved in the conception, design, scale-up, manufacturing, and labeling and packaging processes in the conversion of chemical and biological materials into valuable pharmaceuticals and pharmaceutical therapies.

They have to implement FDA regulations, validation assurance (VA), quality control, and maintain Good Manufacturing Practices (GMP) compliant facilities.

In addition to the safety of the end product, they have to maintain a level of personal and environmental safety.

Arena of 'PHARMACEUTICAL ENGINEER'

- *The following are the necessary areas for Pharmaceutical Engineer:*
- *Technical Knowledge: broad industry knowledge and experience including*
 - *Product development*
 - *Production systems*
 - *Facilities and equipment*
 - *Information systems*
 - *Supply chain management*
 - *Quality systems*
 - *Regulatory compliance*
- *Leadership and Professionalism: cost-effective, risk-based Integration/Innovation/Change Advocacy*
 - *Quality and Continuous Improvement Focus*

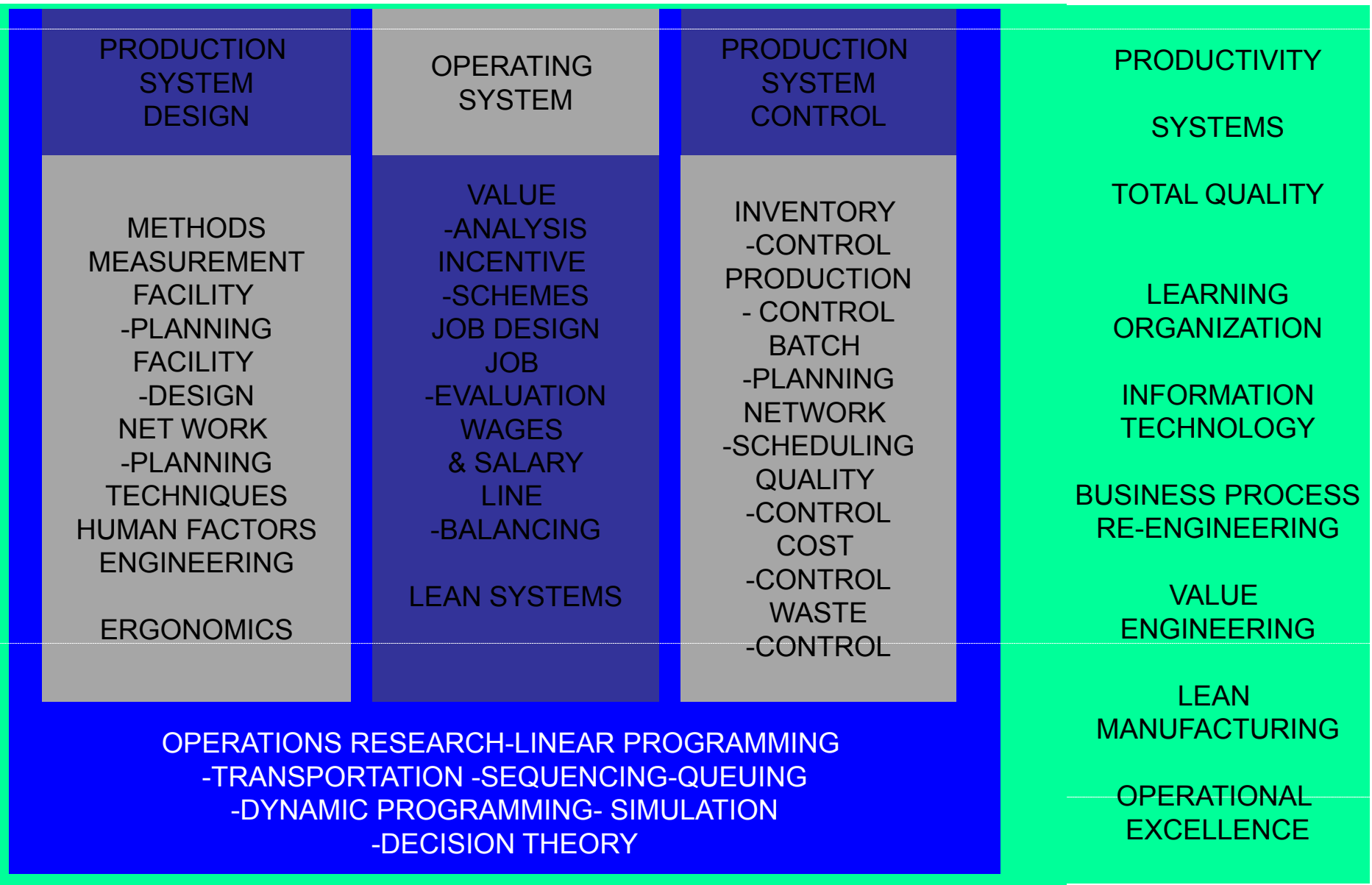
INDUSTRIAL ENGINEERING



AS DEFINED BY AMERICAN INSTITUTE OF INDUSTRIAL ENGINEERING

- *Industrial Engineering is concerned with design, improvement and installation of integrated systems of men, materials and equipments.*
- *It draws upon specialized knowledge and skill in the mathematical, physical and social sciences together with the principles and methods of engineering analysis and design to specify, predict and evaluate the results to be obtained from such systems.*

Arena of 'INDUSTRIAL ENGINEERING'



Stages in PHARMA – Where SPIKE can support

- Research & Development – Stage Gate Mechanism & MIS
- Manufacturing Strategy – Lean, GMP & Operational Excellence
 - Methods, Studies, Scale-up and Manufacturing Plans
 - New Drug Application (NDA) – SOP & GMP
 - Validation and Regulation
- ***5S, Daily Work Management, Value Analysis & Cost Reduction***

WHY SPIKE?

It is difficult to find out opportunities for improvement while doing routine work.

“Too long a familiarity with a problem makes us conservative and some what blind to the possibilities of change and some one from out side can often see things better and more clearly than we can.”

-Sir Walter Worboys of Imperial Chemical Industry

Why SPIKE ?

- If company appoints senior level persons for Industrial engineering, their salaries are prohibitive, the company finds their utility in corporate affairs in very short time, or, because of lack of enough work, they leave early before even contributing to the organization.
- If company appoints junior engineers:-
If they are very good at work, they get promoted and occupy managerial positions and; if they happen to be average, they spoil the work and create new problems which never existed in the company. The junior engineers need guidance from senior persons and failing which, they remain ineffective; the line managers also do not listen to them.

In both the cases, the company has to compromise with the potential profits and which goes on to eroding current profits unless some initiatives are taken to prevent these.

Why SPIKE?

“We are really interested in improvements through use of Industrial Engineering techniques”

The size, of our operations and the organization, restricts us to have separate Pharma-Industrial Engineering Department

Nature of Services offered by SPIKE

High End Services

The Qualitative tasks include:

- Strategy Development & Deployment – Manufacturing & Business
- Stage Gate Mechanism for Research & Development
- Operational Excellence initiatives
- Continuous Improvement Initiatives like DWM, 5S, GMP
- Analytical Services, MIS
- Review and Analysis

Low End Services

The Quantitative tasks include:

- Time & Motion Studies
- Production Norm Setting
- Methods Improvement
- Manpower Rationalization
- PMS
- Create Flow & Pull
- Cost Reduction / optimization
- Layouts
- Standardization

SPIKE : Process specific example....

Continuous Improvement

1

Value Stream Mapping

2

Waste Identification

3

Waste Elimination Process
Design & Implementation

4

Continuous Improvement
Process PDCA

5

Analysis &
Presentation

Management Support

1

Excellence Strategy

2

Excellence Metrics

3

Stage Gate Mechanism

4

Analytical Intelligence

5

Result Compilation - MIS

Proposal

Outsourcing your Pharma-Industrial Engineering Activities – SPIKE – to us.

We expertise in Industrial Engineering – Continuous Improvement & Management Support with thorough Domain Knowledge of Pharma Sector.

We understand your needs.

The MODEL

We will place experienced Industrial engineers in your plant, to carry out day to day industrial engineering related work. Their number will depend on the phase of activities

The strength can also vary with the intensity, speed of improvements desired and the period of life cycle of assignments. It will be mutually agreed at the time of contracting and accepting the assignments. They may be working full time or may be withdrawn as per requirement.

- We have a pool of engineers from specific industries, pharmaceutical fields and work experience in different capacities and trained by us in industrial Engineering.

We will provide services of hard core industrial engineers having experience in relevant field, who will help in finding the most appropriate improvement opportunities in your work areas and supervise the activities of our engineers placed in your plant.

The MODEL

This model has not only inbuilt flexibility but has provision of:

- Increasing the level of activities as per contingency
- Identifying new opportunities and finding solutions for them.
- Implementation of solution can also be the additional responsibility if so desired.
- Diluting the activities if needed, and
- Terminating the contract after mutual consent.

Your Advantages

It brings more riches to the company and stops profit erosion.

You get access to expert services in various disciplines and most appropriate techniques of Industrial Engineering which ensures benefits to the company.

You start getting benefits in less time.

You get expert services within your budget.

Your Advantages

- You need not hire engineers and bother to administer the industrial engineering function.
- You can focus on your core activities and concentrate on increasing competitive capabilities.
- It is very flexible approach to cater to your needs.
- You get many ideas to work on and to set future directions.
- It inspires you to think about improvements and asks to devote some of your time on business improvement.

Preference for SPIKE

- Highly Experienced Professionals
- Qualifications in IE & Management Tools
- Exposure to Pharma Sector
- Optimum use of IE Techniques with skill and understanding of your need
- Can support regional assignments
- Appropriate Staffing to carry out mutually agreed assignments

Where to draw the line?



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