Validation of Pharmaceutical Processes, Equipments/Apparatus, Basic concept in analytical method development for dosage forms, Computer System validation, ERP and SAP systems

Validation of Pharmaceutical Processes, Equipments/Apparatus:-

Introduction

The development of a drug product is a lengthy process involving drug discovery, laboratory testing, animal studies, clinical trials and regulatory registration. To further enhance the effectiveness and safety of the drug product after approval, many regulatory agencies such as the United States Food and Drug Administration (FDA) also require that the drug product be tested for its identity, strength, quality, purity and stability before it can be released for use. For this reason, pharmaceutical validation and process controls are important in spite of the problems that may be encountered1. Process controls include raw materials inspection, in-process controls and targets for final product. The purpose is to monitor the on-line and off-line performance of the manufacturing process and then validate it. Even after the manufacturing process is validated, current good manufacturing practice also requires that a well-written procedure for process controls is established to monitor its performance. This paper provides an overview of pharmaceutical validation and process controls in drug development. The validation concept can be applied to new drugs, new dosage forms and generic drug development.

Essentials of Pharmaceutical Validation

Validation is an integral part of quality assurance; it involves the systematic study of systems, facilities and processes aimed at determining whether they perform their intended functions adequately and consistently as specified. A validated process is one which has been demonstrated to provide a high degree of assurance that uniform batches will be produced that meet the required specifications and has therefore been formally approved. Validation in itself does not improve processes but confirms that the processes have been properly developed and are under control.

Adequate validation is beneficial to the manufacturer in many ways:

- It deepens the understanding of processes; decreases the risk of preventing problems and thus assures the smooth running of the process.

- It decreases the risk of defect costs.
- It decreases the risk of regulatory noncompliance.
- A fully validated process may require less in-process controls and end product testing.

Validation should thus be considered in the following situations:

- Totally new process;
- New equipment;
- Process and equipment which have been altered to suit changing priorities; and
- Process where the end-product test is poor and an unreliable indicator of product quality.

When any new manufacturing formula or method of preparation is adopted, steps should be taken to demonstrate its suitability for routine processing. The defined process should be shown to yield a product consistent with the required quality. In this phase, the extent to which deviations from chosen parameters can influence product quality should also be evaluated. When certain processes or products have been validated during the development stage, it is not always necessary to revalidate the whole process or product if similar equipment is used or similar products have been produced, provided that the final product conforms to the in-process controls and final product specification. There should be a clear distinction between in-process control and validation. In production, tests are performed each time on a batch to batch basis using specifications and methods devised during the development phase. The objective is to monitor the process continuously

Major Phases in Validation

The activities relating to validation studies may be classified into three:

Phase 1*:* This is the Pre-validation Qualification Phase which covers all activities relating to product research and development, formulation pilot batch studies, scale-up studies, transfer of technology to commercial scale batches, establishing stability conditions and storage, and handling of in-process and finished dosage forms, equipment qualification, installation qualification, master production document, operational qualification and process capacity.

Phase 2*:* This is the Process Validation Phase. It is designed to verify that all established limits of the critical process parameter are valid and that satisfactory products can be produced even under the worst conditions.

Phase 3*:* Known as the Validation Maintenance Phase, it requires frequent review of all process related documents, including validation of audit reports, to assure that there have been no changes, deviations, failures and modifications to the production process and that all standard operating procedures (SOPs), including change control procedures, have been followed. At this stage, the validation team comprising of individuals representing all major departments also assures that there have been no changes/deviations that should have resulted in requalification and revalidation5. A

careful design and validation of systems and process controls can establish a high degree of confidence that all lots or batches produced will meet their intended specifications. It is assumed that throughout manufacturing and control, operations are conducted in accordance with the principle of good manufacturing practice (GMP) both in general and in specific reference to sterile product manufacture. The validation steps recommended in GMP guidelines can be summarized as follows

- As a pre-requisite, all studies should be conducted in accordance with a detailed, pre-established **protocol** or series of protocols, which in turn is subject to formal – change control procedures;
- Both the personnel conducting the studies and those running the process being studied should be appropriately **trained** and **qualified** and be suitable and competent to perform the task assigned to them;
- All data generated during the course of studies should be formally **reviewed** and **certified** as evaluated against pre-determined criteria;
- Suitable **testing facilities, equipment, instruments** and **methodology** should be available;
- Suitable clean room facilities should be available in both the 'local' and background environment. There should be assurance that the clean room environment as specified is secured through initial commissioning (qualification) and subsequently through the implementation of a programme of re-testing – in-process equipment should be properly **installed, qualified** and **maintained**;
- When appropriate attention has been paid to the above, the process, if aseptic, may be validated by means of "**process simulation"** studies;
- The process should be revalidated at intervals; and
- Comprehensive **documentation** should be available to define support and record the overall validation process.

Protocols should specify the following in detail:

- The objective and scope of study. There should already be a definition of purpose;
- A clear and precise definition of process equipment system or subsystem, which is to be the subject of study with details of performance characteristics;
- Installation and qualification requirement for new equipment;
- Any upgrading requirement for existing equipment with justification for the change(s) and statement of qualification requirement;
- Detailed stepwise statement of actions to be taken in performing the study (or studies);
- Assignment of responsibility for performing the study;
- Statement on all test methodology to be employed with a precise statement of the test equipment and/or materials to be used;
- Test equipment calibration requirements;
- References to any relevant standard operating procedures (SOP);
- Requirement for the current format of the report on the study;
- Acceptance criteria against which the success (or otherwise) of the study is to be evaluated; and

- The personnel responsible for evaluating and certifying the acceptability of each stage in the study and for the final evaluation and certification of the process as a whole, as measured against the pre-defined criteria.

All personnel involved in conducting the studies should be properly trained and qualified because they can, and often, have a crucial effect on the quality of the end product. All information or data generated as a result of the study protocol should be evaluated by qualified individuals against protocol criteria and judged as meeting or failing the requirements. Written evidence supporting the evaluation and conclusion should be available. If such an evaluation shows that protocol criteria have not been met, the study should be considered as having failed to demonstrate acceptability and the reasons should be investigated and documented. Any failure to follow the procedure as laid down in the protocol must be considered as potentially compromising the validity of the study itself and requires critical evaluation of all the impact on the study. The final certification of the validation study should specify the pre-determined acceptance criteria against which success or failure was evaluated.

Validation of Analytical Assays and Test Methods

Method validation confirms that the analytical procedure employed for a specific test is suitable for its intended use. The validation of an analytical method is the process by which it is established by laboratory studies that the performance characteristics of the method meet the requirement for the intended application. This implies that validity of a method can be demonstrated only though laboratory studies.

Methods should be validated or revalidated:

- before their introduction and routine use;
- whenever the conditions change for which the method has been validated, e.g., instrument with different characteristics; and
- wherever the method is changed and the change is outside the original scope of the method.

Strategy for Validation of Methods

The validity of a specific method should be demonstrated in laboratory experiments using samples or standards that are similar to the unknown samples analyzed in the routine. The preparation and execution should follow a validation protocol preferably written in a step-by-step instruction format as follows:

- Develop a validation protocol or operating procedure for the validation;
- Define the application purpose and scope of the method;
- Define the performance parameters and acceptance criteria;
- Define validation experiments;
- Verify relevant performance characteristics of the equipment;
- Select quality materials, e.g., standards and reagents;
- Perform pre-validation experiments;
- Adjust method parameters and/or acceptance criteria, if necessary;
- Perform full internal (and external) validation experiments;
- Develop SOPs for executing the method routinely;

- Define criteria for revalidation;
- Define type and frequency of system suitability tests and/or analytical quality control (AQC) checks for the routine; and
- Document validation experiments and results in the validation report.

Environmental Considerations: Cleaning and Clean Room Standards

Cleaning validation is documented proof that one can consistently and effectively clean a system or equipment items. The procedure is necessary for the following reasons:

- It is a customer requirement – it ensures the safety and purity of the product;
- It is a regulatory requirement in active pharmaceutical product manufacture;
- It also assures from an internal control and compliance point of view the quality of the process.

The FDA guide to inspections intended to cover equipment cleaning (chemical residues only) expects firms to have written procedure (SOPs) detailing the cleaning processes and also written general procedure on how cleaning processes will be validated. FDA expects a final validation report which is approved by management and which states whether or not the cleaning process is valid. The data should support a conclusion that residues have been reduced to an "acceptable level". Harder cited five crucial elements:

1. A standard operating procedure (SOP) for cleaning with a checklist;
2. A procedure for determining cleanliness (rinse or swab);
3. An assay for testing residual drug levels;
4. Pre-set criteria for testing chemical and microbial limit to which to equipment must be cleaned; and
5. Protocol for cleaning validation.

Harder recommended that the procedure be tested for, requiring it to be successful on three successive cleanings and there should be periodic revalidation as well as revalidation after significant changes.

Jenkins and Vanderwielen presented an overview of cleaning validation covering strategy and determination of residue limits, method of sampling and analysis noting that "increased use of multipurpose equipment" has produced increased interest in cleaning validation. The cleaning protocol must be thorough and must be checked. Training is essential. A validation program requires

- criteria for acceptance after cleaning,
- appropriate methods of sampling,
- a maximum limit set for residues, and
- test methods that must themselves be tested.

Products to be tested may be put into groups rather than testing all of them. The most important may not be the highest volume product but those capable of causing the largest possible problems if contaminated or if they contaminate the products (solubility of the drug is an important issue). Equipment may also be tested in groups.

Process Validation

Process validation is the means of ensuring and providing documentary evidence that processes (within their specified design parameters) are capable of repeatedly and reliably producing a finished product of the required quality5. It would normally be expected that process validation be completed prior to the release of the finished product for sale (prospective validation). Where this is not possible, it may be necessary to validate processes during routine production (concurrent validation). Processes, which have been in use for sometime without any significant changes, may also be validated according to an approved protocol (retrospective validation).

Pre-requisites for Process Validation

Before process validation can be started, manufacturing equipment and control instruments as well as the formulation must be qualified. The information on a pharmaceutical product should be studied in detail and qualified at the development stage, i.e., before an application for marketing authorization is submitted. This involves studies on the compatibility of active ingredients and recipients, and of final drug product and packaging materials, stability studies, etc. Other aspects of manufacture must be validated including critical services (water, air, nitrogen, power supply, etc.) and supporting operations such as equipment cleaning and sanitation of premises. Proper training and motivation of personnel are prerequisites to successful validation.

The Pharmaceutical Process Equipment

The key idea of validation is to provide a high level of documented evidence that the equipment and the process conform to a written standard. The level (or depth) is dictated by the complexity of the system or equipment. The validation package must provide the necessary information and test procedures required to provide that the system and process meet specified requirements. Validation of pharmaceutical process equipment involves the following:

- **Installation Qualification:**

This ensures that all major processing and packaging equipment, and ancillary systems are in conformity with installation specification, equipment manuals schematics and engineering drawing. It verifies that the equipment has been installed in accordance with manufacturers recommendation in a proper manner and placed in an environment suitable for its intended purpose.

- **Operational Qualification:**

This is done to provide a high degree of assurance that the equipment functions as intended. Operational qualification should be conducted in two stages:

- **Component Operational Qualification**, of which calibration can be considered a large part.
- **System Operational Qualification,**to determine if the entire system operates as an integrated whole.

- **Process Performance Qualification:** This verifies that the system is repeatable and is consistently producing a quality product.

These exercises assure, through appropriate performance lists and related documentation, that equipment, ancillary systems and sub-systems have been commissioned correctly. The end results are that all future operations will be reliable and within prescribed operational limits. At various stages in a validation exercise there are needs for protocols, documentation, procedures, specifications and acceptance criteria for test results. All these need to be reviewed, checked and authorized. It would be expected that representatives from the professional disciplines, e.g., engineering, research and development, manufacturing, quality control and quality assurance are actively involved in these undertakings with the final authorization given by a validation team or the quality assurance representative.

Approaches to Validation Process

There are two basic approaches to the validation of the process itself (apart from the qualification of equipment used in production, the calibration of control and measurement instruments, the evaluation of environmental factors, etc). These are the experimental approach and the approach based on the analysis of historical data. The experimental approach, which is applicable to both prospective and concurrent validation, may involve

- extensive product testing,
- simulation process trials,
- challenge/worst case trials, and
- control of process parameters (mostly physical).

One of the most practical forms of process validation, mainly for non-sterile products, is the final testing of the product to the extent greater than that required in routine quality control. It may involve extensive sampling, far beyond that called for in routine quality control and specifications, and often for certain parameters only. Thus, for instance, several hundred tablets per batch may be weighed to determine unit dose uniformity. The results are then treated statistically to verify the normality of the distribution and to determine the standard deviation from the average weight. Confidence limits for individual results and for batch homogeneity are also estimated. Strong assurance is provided that samples taken at random will meet regulatory requirements if the confidence limits are within compendial specifications.

In the approach based on analysis of historical data, no experiments are performed in retrospective validation, but instead all available historical data concerning a number of batches are combined and jointly analysed, if production is proceeding smoothly during the period preceding validation and the data in process inspection and final testing of the product are combined and treated statistically. The results including the outcome of process capability studies, trend analysis, etc., will indicate whether the process is under control or not.

Expert Evaluation

This is an evaluation of the entire study against the protocol requirements as outlined above. It should be prepared and the conclusion drawn at each stage stated. The final conclusions should reflect whether the protocol requirements were met. The evaluation should include an assessment of the planned calibration and maintenance programmes for the equipment and instrumentation to maintain the validated conditions. In addition, all process monitoring and control procedures required to routinely ensure that the validated conditions are maintained should be reported. The evaluation should be signed by authorized officers of the organization who were members of the team establishing the protocol and who have appropriate expertise in the area assigned to them. Overall approval of the study should be authorized by the head of the validation team and the head of the quality control department.

The Validation Report

A written report should be available after completion of the validation. If found acceptable, it should be approved and authorized (signed and dated). The report should include at least the following:

- Title and objective of study;
- Reference to protocol;
- Details of material;
- Equipment;
- Programmes and cycles used;
- Details of procedures and test methods;
- Results (compared with acceptance criteria); and
- Recommendations on the limit and criteria to be applied on future basis.

Analytical Methods Development and Validation :-

Play important roles in the discovery, development, and manufacture of pharmaceuticals. The official test methods that result from these processes are used by quality control laboratories to ensure the identity, purity, potency, and performance of drug products.

In recent years, a great deal of effort has been devoted to the harmonization of pharmaceutical regulatory requirements in the United States, Europe, and Japan. As part of this initiative, the International Conference on Harmonization (ICH) has issued guidelines for analytical method validation. The recent FDA methods validation draft guidance document as well as *USP* both refer to ICH guidelines (2). Analytical guidance documents recently published by the ICH are the following:

- stability testing (Q1)
- validation of analytical procedures (Q2)
- impurities in drug substances and products (Q3)
- specifications for new drug substances and products (Q6).

Additional regulatory guidance can be found on the FDA Web site www.fda.gov/cder/guidance and on the ICH Web site www.ich.org. These sites ensure access to current methods development and validation guidelines. The methods validation documentation requirements for IND and NDA submissions are outlined in the chemistry, manufacturing and controls (CMC) guidance document (2). The current trend continues to be in the direction of phase-dependent methods development and validation. Nonvalidated screening methods are used to monitor the synthesis of active ingredients or to confirm their identity during discovery and preclinical research. Analytical methods are progressively optimized and a preliminary validation package is furnished as part of the IND application before Phase I safety trials are initiated. All analytical methods should be fully optimized and validation completed before the NDA is submitted at the end of Phase III studies. Method validation is a continuous process. The goal is to ensure confidence in the analytical data throughout product development.

The method development and validation processes

The steps of methods development and method validation depend upon the type of method being developed However, the following steps are common to most types of projects:

- method development plan definition
- background information gathering
- laboratory method development
- generation of test procedure
- methods validation protocol definition
- laboratory methods validation
- validated test method generation
- validation report.

A well-developed method should be easy to validate. A method should be developed with the goal to rapidly test preclinical samples, formulation prototypes, and commercial samples. As the methods development and validation processes advance, the information gathered is captured in the design and subsequent improvement of the method. Ideally, the validation protocol should be written only following a thorough understanding of the method's capabilities and intended use. The validation protocol will list the acceptance criteria that the method can meet. Any failure to meet the criteria will require that a formal investigation be conducted. The required validation parameters, also termed *analytical performance characteristics*, depend upon the type of analytical method. Pharmaceutical analytical methods are categorized into five general types (3):

- identification tests
- potency assays
- impurity tests: quantitative
- impurity tests: limit
- specific tests.

The first four tests are universal tests, but the specific tests such as particle-size analysis and X ray diffraction are used to control specific properties of the active pharmaceutical ingredient (API) or the drug product. Validation requirements depend upon the type of test method, including

- *specificity:* ability to measure desired analyte in a complex mixture
- *accuracy:* agreement between measured and real value
- *linearity:* proportionality of measured value to concentration
- *precision:* agreement between a series of measurements
- *range:* concentration interval where method is precise, accurate, and linear
- *detection limit:* lowest amount of analyte that can be detected
- *quantitation limit:* lowest amount of analyte that can be measured
- *robustness:* reproducibility under normal but variable laboratory conditions.

Only specificity is needed for an identification test. However, the full range of specificity, accuracy, linearity, range, limit of detection (LOD), limit of quantitation (LOQ), precision, and robustness testing is needed for more-complex methods such as quantitative impurity methods. The validated test method is included in the validation report that summarizes the results of the validation studies. Both the validation report and test method are submitted as parts of the NDA or ANDA.

Advances in technology and equipment

Recent progress in methods development has been largely a result of improvements in analytical instrumentation. This is especially true for chromatographs and detectors. Isocratic and gradient reverse-phase HPLC have evolved as the primary techniques for the analysis of nonvolatile APIs and impurities. The HPLC detector of choice for many types of methods development is the photodiode array (PDA) detector because it can be used for both quantitative and qualitative analysis. The use of a PDA detector to determine peak purity of the active ingredient in stressed samples greatly facilitates the development of stability-indicating assays. The emphasis on the identification of trace impurities and degradants has led to the increased use of hyphenated techniques such as liquid chromatography–mass spectrometry (LC–MS) and liquid chromatography–nuclear magnetic resonance

spectroscopy (LC–NMR). This trend will continue with the need to better define degradation pathways. The ultraviolet (UV) absorbance detector remains the most common HPLC detector for potency and impurity analysis. Once specificity has been demonstrated, the PDA detector is replaced with a variable wavelength detector and the HPLC effluent is monitored at fixed wavelengths. Stability-indicating and impurity methods often are required to measure analytes within a wide concentration range. For example, process impurities and/or degradation products may be present at levels of 0.1%, and the main active ingredient typically is present at the nominal concentration (100%). This amount is well within the linear range of a fixed wavelength detector but not within the linear range for LC–MS detectors. Recent FDA and ICH guidance about chiral drug products and impurities has posed new challenges for methods development scientists (3). However, recent advances in the use of chiral HPLC columns has greatly facilitated progress in this area. The advances are primarily a result of the introduction of chiral stationary phases (CSPs) prepared by reacting amylose or cellulose derivatives with silica. The new CSPs allow trace levels of enantiomeric impurities to be measured. Gas chromatography remains the method of choice for the analysis of volatile compounds. Gas chromatography with mass spectrometry detection (GC–MS) is increasingly being used to identify impurities and to determine active ingredient peak purity in stressed samples. Advances in laboratory robotics and automation also are beginning to be applied to methods development and validation. Development teams are using laboratory robotics to develop automated methods for high-volume tests. An in-depth review of all the recent advances in analytical instrumentation is beyond the scope of this article. However, several methods should be noted. Advances in the use of nondestructive infrared (IR) and near-infrared spectroscopy (near IR) and NMR techniques are particularly promising for methods development scientists.

Issues and challenges

For a methods development and validation program to be successful, a holistic approach is recommended. A common challenge encountered during methods development and validation is that methods are typically developed by the R&D department, whereas validation is typically the responsibility of a validation group. It's important that the R&D and validation groups work as one team. Various groups also may be responsible for ensuring the suitability of the methods to support early clinical phases and commercial manufacturing. The transfer of analytical methods from one group to another then becomes an important step for ensuring that the proper validation is in place to justify its intended use. Because the method will be run by several groups during its progression from development to validation, the method must be robust. This means the method should provide reliable data, both on a wide range of equipment and in the hands of several chemists. A common weakness in development and validation of methods is that the methods are not robust enough. If robustness is not built into methods early in development, then the result most likely will be loss of efficiency during routine QC testing and a lengthy and complicated validation process as well. Another challenge encountered early in the development of methods intended to support stability studies is ensuring that the method is stability indicating. This process is typically achieved by conducting forced-degradation studies. The design and execution of these studies requires thorough knowledge of the product being tested as well as a good understanding of the analysis technique.

As mentioned previously, new regulatory guidelines are being published governing the expectations of regulatory agencies throughout the world for methods development and validation. Another challenge is that many pharmaceutical companies must upgrade methods to meet current regulatory standards. From a simple method improvement to a complete redevelopment and subsequent cross-over to an older method, the upgrade of analytical methods can be a daunting task. For this reason, one must be alert to current trends in regulatory guidelines and to adopt a proactive approach to changes that may affect development and validation programs. Finally, one of the key requirements for methods validation (which is also one of the key challenges), is that only well-characterized reference materials with well documented purities should be used during method validation activities. The challenge stems from the fact that, in some cases, the tools used to characterize reference standard materials are being developed and validated at the same time as the reference standard itself.

Conclusion

The efficient development and validation of analytical methods are a critical elements in the development of pharmaceuticals. Success in these areas can be attributed to several important factors, which in turn will contribute to regulatory compliance. Experience is one of these factors—both the experience level of the individual scientists and the collective experience level of the development and validation department. A strong mentoring and training program is another important factor for ensuring successful methods development and validation. Companies must maintain an appropriate level of expertise in this important dimension of developing safe and effective drugs.

Computer System Validation:-

This guide was developed as a resource document to assist regulated industry Validation, Quality Assurance, Technical Services, and regulated industry professionals to identify and adapt "best practices" in their management of validation and qualification of computer systems, software, hardware and developmental practices and activities.

This guide was developed to be a concise, step-by-step set of management aids, which are consistent with industry standards. They are designed to guide implementation to the minimum recommended level of practices and standards. Local management, at its discretion, may decide that these recommended levels are insufficient for local conditions and needs and therefore require more stringent practices and controls.

The practices within the guides, when fully implemented will serve to ensure secure and cost effective operation and evolution of protocol implementation.

Suggestions for improvement to this guide are always welcome. This document is intended to be living document and will be upgraded and adapted as 'better practices' emerges.

Introduction

This introduction provides an overview of the Computer System Validation Corporate Computer System Validation (CSV) Guide.

Process Validation

In 1987 the Food and Drug Administration published a document entitled
'*FDA Guidelines on General Principles of Process Validation'.*

It states the following:

Process validation is establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes.

Note: This definition indicates that validation can apply to any process including process managed/controlled by computer systems.

Validation

Validation is applied to many aspects of the healthcare and other regulated industries and businesses.

Examples include:

• services • equipment • computer systems • processes • cleaning

In each case, the objective of validation is to produce documented evidence, which provides a high degree of assurance that all parts of the facility will consistently work correctly when brought into use.

Note: Validation requires documented evidence, if the validation process is not documented then it cannot be proved to have occurred.

Scope

This guide looks at computer systems validation only. Computer systems validation includes validation of both new and existing computer systems.

Definition of computer system

For the purposes of this guide, a computer system is defined as:

any programmable device including its software, hardware, peripherals, procedures, users, interconnections and inputs for the electronic processing and output of information used for reporting or control.

Examples of computer systems

Examples of computer systems include:

· automated manufacturing equipment

· control systems

· automated laboratory equipment

· laboratory data capture system

· manufacturing execution systems

· computers running laboratory, clinical or manufacturing database systems

Purpose

The purpose of this guide is to help you:

· identify computer systems that require validation

· determine how to validate, and the extent of validation required, for the computer systems that have been identified

· comply with the validation requirements documented in the (CSV) in accordance with your Company's Software Systems Development Master Plan (SDMP).

Audience

This guide is intended for:

· Information Resources, Services and Technology members

· all concerned managers, auditors and regulatory personnel

· all developers of computer systems applications

· all personnel involved in computer systems procurement

· all users of computer systems involved in validation activities

Use of Standard terms

The terms and meanings in the Glossary have been adopted as a standard for use within this guide.

Consistent use of these terms will facilitate communication about computer system validation throughout the Company.

Enterprise Resource Planning (ERP):-

It is an integrated computer-based system used to manage internal and external resources including tangible assets, financial resources, materials, and human resources. It is a software architecture whose purpose is to facilitate the flow of information between all business functions inside the boundaries of the organization and manage the connections to outside stakeholders. Built on a centralized database and normally utilizing a common computing platform, ERP systems consolidate all business operations into a uniform and enterprise wide system environment.

An ERP system can either reside on a centralized server or be distributed across modular hardware and software units that provide "services" and communicate on a local area network. The distributed design allows a business to assemble modules from different vendors without the need for the placement of multiple copies of complex, expensive computer systems in areas which will not use their full capacity

ERP Components

Transactional Backbone

- Financials
- Distribution
- Human Resources
- Product lifecycle management

Advanced Applications

- Customer Relationship Management (CRM)
- Supply chain management
  - Purchasing
  - Manufacturing
  - Distribution
- Warehouse Management System

Management Portal/Dashboard

- Decision Support System

These modules can exist in a complete system or utilized in an ad-hoc fashion.

Commercial Applications

Manufacturing

Engineering, bills of material, scheduling, capacity, workflow management, quality control, cost management, manufacturing process, manufacturing projects, manufacturing flow

Supply chain management

Order to cash, inventory, order entry, purchasing, product configurator, supply chain planning, supplier scheduling, inspection of goods, claim processing, commission calculation

Financials

General ledger, cash management, accounts payable, accounts receivable, fixed assets

Project management

Costing, billing, time and expense, performance units, activity management

Human resources

Human resources, payroll, training, time and attendance, rostering, benefits

Customer relationship management

Sales and marketing, commissions, service, customer contact and call center support

Data services

Various "self-service" interfaces for customers, suppliers, and/or employees

Access control

Management of user privileges for various processes

Implementation

Businesses have a wide scope of applications and processes throughout their functional units; producing ERP software systems that are typically complex and usually impose significant changes on staff work practices. Implementing ERP software is typically too complex for "in-house" skill, so it is desirable and highly advised to hire outside consultants who are professionally trained to implement these systems. This is typically the most cost effective way. There are three types of services that may be employed for - Consulting, Customization, Support. The length of time to implement an ERP system depends on the size of the business, the number of modules, the extent of customization, the scope of the change and the willingness of the customer to take ownership for the project. ERP systems are modular, so they don't all need be implemented at once. It can be divided into various stages, or phase-ins. The typical project is about 14 months and requires around 150 consultants. A small project (e.g., a company of less than 100 staff) can be planned and delivered within 3–9 months; however, a large, multi-site or multi-country implementation can take years. The length of the implementations is closely tied to the amount of customization desired.

To implement ERP systems, companies often seek the help of an ERP vendor or of third-party consulting companies. These firms typically provide three areas of professional services: consulting; customization; and support. The client organization can also employ independent program management, business analysis, change management, and UAT specialists to ensure their business requirements remain a priority during implementation.

Data migration is one of the most important activities in determining the success of an ERP implementation. Since many decisions must be made before migration, a significant amount of planning must occur. Unfortunately, data migration is the last activity before the production phase of an ERP implementation, and therefore receives minimal attention due to time constraints. The following are steps of a data migration strategy that can help with the success of an ERP implementation:

1. Identifying the data to be migrated
2. Determining the timing of data migration
3. Generating the data templates
4. Freezing the tools for data migration
5. Deciding on migration related setups
6. Deciding on data archiving

Process preparation

ERP vendors have designed their systems around standard business processes, based upon best business practices. Different vendor(s) have different types of processes but they are all of a standard, modular nature. Firms that want to implement ERP systems are consequently forced to adapt their organizations to standardized processes as opposed to adapting the ERP package to the existing processes. Neglecting to map current business processes prior to starting ERP implementation is a main reason for failure of ERP projects. It is therefore crucial that organizations perform a thorough business process analysis before selecting an ERP vendor and setting off on the implementation track. This analysis should map out all present operational processes, enabling selection of an ERP vendor whose standard modules are most closely aligned with the established organization. Redesign can then be implemented to achieve further process congruence. Research indicates that the risk of business process mismatch is decreased by:

- linking each current organizational process to the organization's strategy;
- analyzing the effectiveness of each process in light of its current related business capability;
- understanding the automated solutions currently implemented.

ERP implementation is considerably more difficult (and politically charged) in organizations structured into nearly independent business units, each responsible for their own profit and loss, because they will each have different processes, business rules, data semantics, authorization hierarchies and decision centers. Solutions include requirements coordination negotiated by local change management professionals or, if this is not possible, federated implementation using loosely

integrated instances (e.g. linked via Master Data Management) specifically configured and/or customized to meet local needs.

A disadvantage usually attributed to ERP is that business process redesign to fit the standardized ERP modules can lead to a loss of competitive advantage. While documented cases exist where this has indeed materialized, other cases show that following thorough process preparation ERP systems can actually increase sustainable competitive advantage.

Configuration

Configuring an ERP system is largely a matter of balancing the way you want the system to work with the way the system lets you work. Begin by deciding which modules to install, then adjust the system using configuration tables to achieve the best possible fit in working with your company's processes.

Modules — Most systems are modular simply for the flexibility of implementing some functions but not others. Some common modules, such as finance and accounting are adopted by nearly all companies implementing enterprise systems; others however such as human resource management are not needed by some companies and therefore not adopted. A service company for example will not likely need a module for manufacturing. Other times companies will not adopt a module because they already have their own proprietary system they believe to be superior. Generally speaking the greater number of modules selected, the greater the integration benefits, but also the increase in costs, risks and changes involved.

Configuration Tables – A configuration table enables a company to tailor a particular aspect of the system to the way it chooses to do business. For example, an organization can select the type of inventory accounting – FIFO or LIFO – it will employ or whether it wants to recognize revenue by geographical unit, product line, or distribution channel.

So what happens when the options the system allows just aren't good enough? At this point a company has two choices, both of which are not ideal. It can re-write some of the enterprise system's code, or it can continue to use an existing system and build interfaces between it and the new enterprise system. Both options will add time and cost to the implementation process. Additionally they can dilute the system's integration benefits. The more customized the system becomes the less possible seamless communication between suppliers and customers

Consulting services

Many organizations do not have sufficient internal skills to implement an ERP project. This results in many organizations offering consulting services for ERP implementation. Typically, a consulting team is responsible for the entire ERP implementation including:

1. selecting
2. planning
3. training
4. testing

5. implementation 6. delivery

of any customized modules. Examples of customization includes creating processes and reports for compliance, additional product training; creation of process triggers and workflow; specialist advice to improve how the ERP is used in the business; system optimization; and assistance writing reports, complex data extracts or implementing Business Intelligence

For most mid-sized companies, the cost of the implementation will range from around the list price of the ERP user licenses to up to twice this amount (depending on the level of customization required). Large companies, and especially those with multiple sites or countries, will often spend considerably more on the implementation than the cost of the user licenses—three to five times more is not uncommon for a multi-site implementation.

Unlike most single-purpose applications, ERP packages have historically included full source code and shipped with vendor-supported team IDEs for customizing and extending the delivered code. During the early years of ERP the guarantee of mature tools and support for extensive customization was an important sales argument when a potential customer was considering developing their own unique solution in-house, or assembling a cross-functional solution by integrating multiple "best of breed" applications.

"Core system" customization vs configuration

Increasingly, ERP vendors have tried to reduce the need for customization by providing built-in "configuration" tools to address most customers' needs for changing how the out-of-the-box core system works. Key differences between customization and configuration include:

- Customization is always optional, whereas some degree of configuration (e.g., setting up cost/profit centre structures, organisational trees, purchase approval rules, etc.) may be needed before the software will work at all.
- Configuration is available to all customers, whereas customization allows individual customer to implement proprietary "market-beating" processes.
- Configuration changes tend to be recorded as entries in vendor-supplied data tables, whereas customization usually requires some element of programming and/or changes to table structures or views.
- The effect of configuration changes on the performance of the system is relatively predictable and is largely the responsibility of the ERP vendor. The effect of customization is unpredictable and may require time-consuming stress testing by the implementation team.
- Configuration changes are almost always guaranteed to survive upgrades to new software versions. Some customizations (e.g. code that uses pre-defined "hooks" that are called before/after displaying data screens) will survive upgrades, though they will still need to be re-tested. More extensive customizations (e.g. those involving changes to fundamental data structures) will be overwritten during upgrades and must be re-implemented manually.

By this analysis, customizing an ERP package can be unexpectedly expensive and complicated, and tends to delay delivery of the obvious benefits of an integrated system. Nevertheless, customizing an ERP suite gives the scope to implement secret recipes for excellence in specific areas while ensuring that industry best practices are achieved in less sensitive areas.

Extensions

In this context, "Extensions" refers to ways that an ERP environment can be "extended" (supplemented) with third-party programs. It is technically easy to expose most ERP transactions to outside programs that do other things, e.g.:

- archiving, reporting and republishing (these are easiest to achieve, because they mainly address static data);
- performing transactional data captures, e.g. using scanners, tills or RFIDs (also relatively easy because they touch existing data);

However, because ERP applications typically contain sophisticated rules that control how data can be created or changed, some such functions can be very difficult to implement.

Advantages

In the absence of an ERP system, a large manufacturer may find itself with many software applications that cannot communicate or interface effectively with one another. Tasks that need to interface with one another may involve:

- ERP systems connect the necessary software in order for accurate forecasting to be done. This allows inventory levels to be kept at maximum efficiency and the company to be more profitable.
- Integration among different functional areas to ensure proper communication, productivity and efficiency
- Design engineering (how to best make the product)
- Order tracking, from acceptance through fulfillment
- The revenue cycle, from invoice through cash receipt
- Managing inter-dependencies of complex processes bill of materials
- Tracking the three-way match between purchase orders (what was ordered), inventory receipts (what arrived), and costing (what the vendor invoiced)
- The accounting for all of these tasks: tracking the revenue, cost and profit at a granular level.

ERP Systems centralize the data in one place. Benefits of this include:

- Eliminates the problem of synchronizing changes between multiple systems - consolidation of finance, marketing and sales, human resource, and manufacturing applications
- Permits control of business processes that cross functional boundaries

- Provides top-down view of the enterprise (no "islands of information"), real time information is available to management anywhere, anytime to make proper decisions.
- Reduces the risk of loss of sensitive data by consolidating multiple permissions and security models into a single structure.
- Shorten production leadtime and delivery time
- Facilitating business learning, empowering, and building common visions

Some security features are included within an ERP system to protect against both outsider crime, such as industrial espionage, and insider crime, such as embezzlement. A data-tampering scenario, for example, might involve a disgruntled employee intentionally modifying prices to below-the-breakeven point in order to attempt to interfere with the company's profit or other sabotage. ERP systems typically provide functionality for implementing internal controls to prevent actions of this kind. ERP vendors are also moving toward better integration with other kinds of information security tools.

Disadvantages

Problems with ERP systems are mainly due to inadequate investment in ongoing training for the involved IT personnel - including those implementing and testing changes - as well as a lack of corporate policy protecting the integrity of the data in the ERP systems and the ways in which it is used.

Disadvantages

- Customization of the ERP software is limited.
- Re-engineering of business processes to fit the "industry standard" prescribed by the ERP system may lead to a loss of competitive advantage.
- ERP systems can be very expensive (This has led to a new category of "ERP light" solutions)
- ERPs are often seen as too rigid and too difficult to adapt to the specific workflow and business process of some companies—this is cited as one of the main causes of their failure.
- Many of the integrated links need high accuracy in other applications to work effectively. A company can achieve minimum standards, then over time "dirty data" will reduce the reliability of some applications.
- Once a system is established, switching costs are very high for any one of the partners (reducing flexibility and strategic control at the corporate level).
- The blurring of company boundaries can cause problems in accountability, lines of responsibility, and employee morale.
- Resistance in sharing sensitive internal information between departments can reduce the effectiveness of the software.
- Some large organizations may have multiple departments with separate, independent resources, missions, chains-of-command, etc, and consolidation into a single enterprise may yield limited benefits.