- The component/function manages records that support the process of annual reviews or batch yield calculations.
- The component/function manages data that are used to create labels that identify a drug substance, intermediate, commercial product, clinical material or drug product.
- The component/function manages data that are part of the batch record or used to support lot release.
- The component/function generates, stores or transmits data used to support quality decisions related to product quality;

Examples:

- The component/function is used for evaluation of acceptance/rejection of raw materials, in-process materials or final products (e.g. laboratory test result values).
- The component/function is used in demonstrating compliance with a registered process. The term ñregistered processò refers to documents filed with regulatory agencies (e.g. an artwork system storing the sizes and colors of packaging material).
- The system generates, stores or transmits product status (e.g. released versus quarantined).

Definition:

1. Critical Data are defined as data that are used to accept or reject product or material, to support decisions related to product quality, or to support Regulatory Compliance Practices.

2. The term ñprimaryò record is used to exclude systems that are used to create a paper document, where the paper document is the primary document

Critical Components

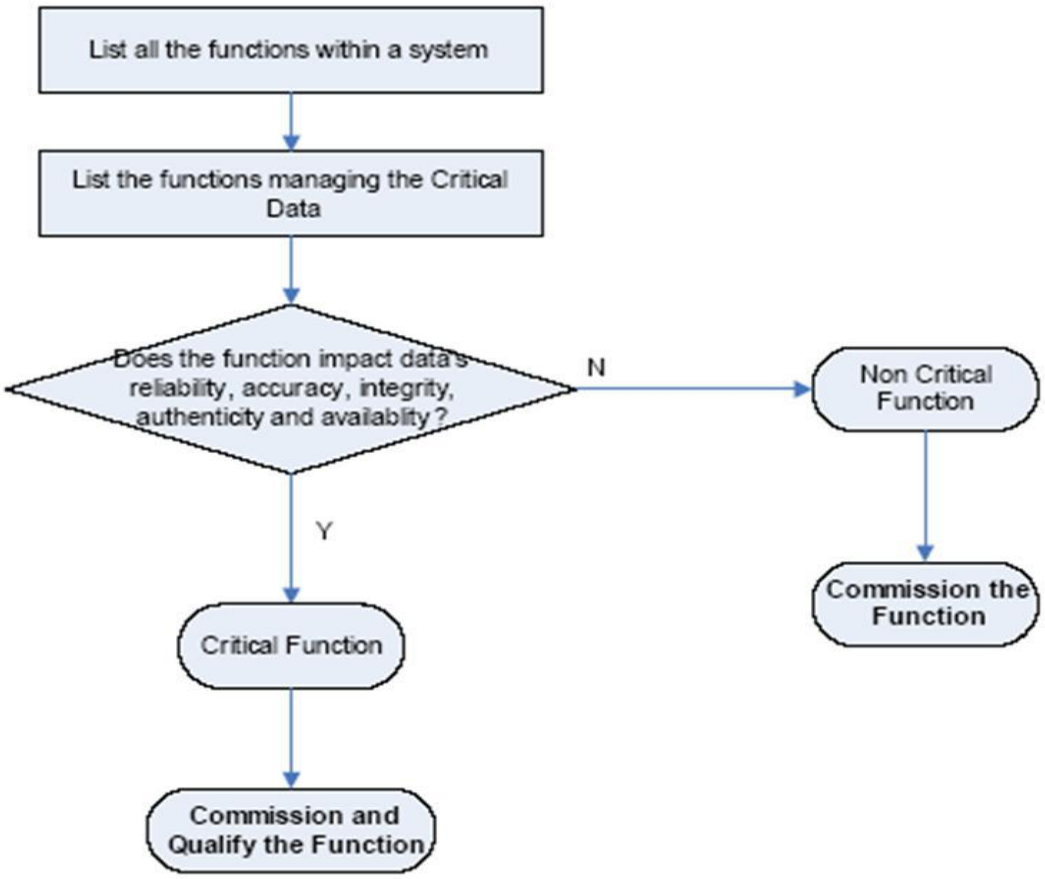
A Critical Component can be defined as a physical element or function of a system where operations, contact, data, control, alarm or failure directly impacts product quality or regulatory compliance.

A non-critical component is defined as a physical element or function of a system where the operation, contact, data, control, alarm, or failure will have no impact on product quality or regulatory compliance practices.

For Information Systems, critical and non-critical components are best categorized as critical and non-critical functions. A critical function can be defined as any of the following:

- Å A function within a direct impact system used to support the manufacturing, processing, packaging, labeling, testing, holding or distribution of a material or product, that has a direct impact on a productôs safety, identity, strength, quality, purity, status or traceability; or
- Å A function within a direct impact system used to support the manufacturing, processing, packaging, labeling, testing, holding or distribution of a material or product, that has a direct impact on regulatory compliance practices.

If a system has one or more critical functions then it is, by definition, a Direct Impact System. Direct Impact Systems manage Critical Data. Only Direct Impact Systems can have critical components. The CLIA should only assess functions that manage Critical Data.



Identification of Components

One of the challenges in performing Component Level Impact Assessment is identifying individual components (functions) in software products. An approach for identifying components includes identifying each (numbered) Specification item (e.g. Functional Specification) as a component.

1. Example for a LIMS system (Note: This is just an example only. Not all the functions within a LIMS system are listed below):

	Component (Function)	Critical	Rationale
1)	Certificate of analysis (CoA) report functionality	Y	C of A report functionality outputs Critical Data.
2)	Sample analysis report functionality	Y	Sample analysis report functionality outputs Critical Data (used to accept/reject product)
3)	Stability summary report functionality	Y	Stability summary report functionality outputs Critical Data that support regulatory compliance practices

10)	The system will require a user to change their password after a pre-defined period of time.	Y	This functionality protects Critical Data from unauthorized medication.
11)	System will record a history for a production plan	Y	This functionality ensures authenticity of Critical Data.
12)	Print a production plan	Y	This functionality outputs Critical Data.
The assessment above results in the conclusion that functions 1) to 7) need to be commissioned, while functions 8) to 12) require commissioning and qualification.			

3. Example for a Training System (Note: This is just an example only. Not all the functions within a Training system are listed below): **Component (Function) Critical Rationale**

	Component (Function)	Critical	Rationale
1)	The training module will be identified by a unique module identifier, title and date.	N	This functionality does not affect Critical Data.
2)	The training module identifier will include a revision code.	N	This functionality does not affect Critical Data.
3)	The training module must be accessible on companyôs Intranet.	N	This functionality does not affect Critical Data.
4)	The training module must be able to support multiple simultaneous users.	N	This functionality does not affect Critical Data.
5)	System access is limited to authorized individuals.	Y	This functionality protects Critical Data from unauthorized medication.
6)	The training module will automatically print the ñLaboratory Analyst Training Recordò report for users who passed the Test.	Y	This functionality outputs Critical Data.
The assessment above results in the conclusion that functions 1) to 4) need to be commissioned, while functions 5) to 6) require commissioning and qualification.			

