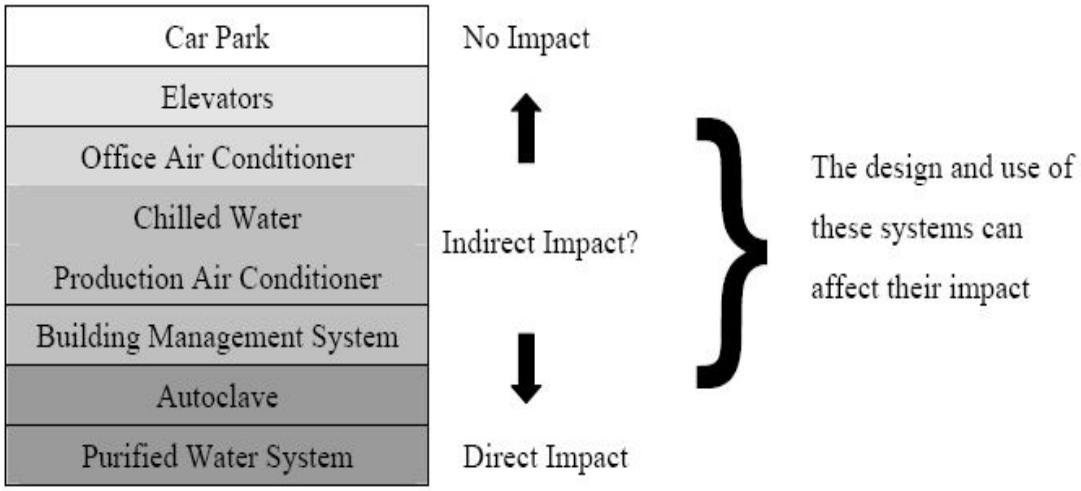
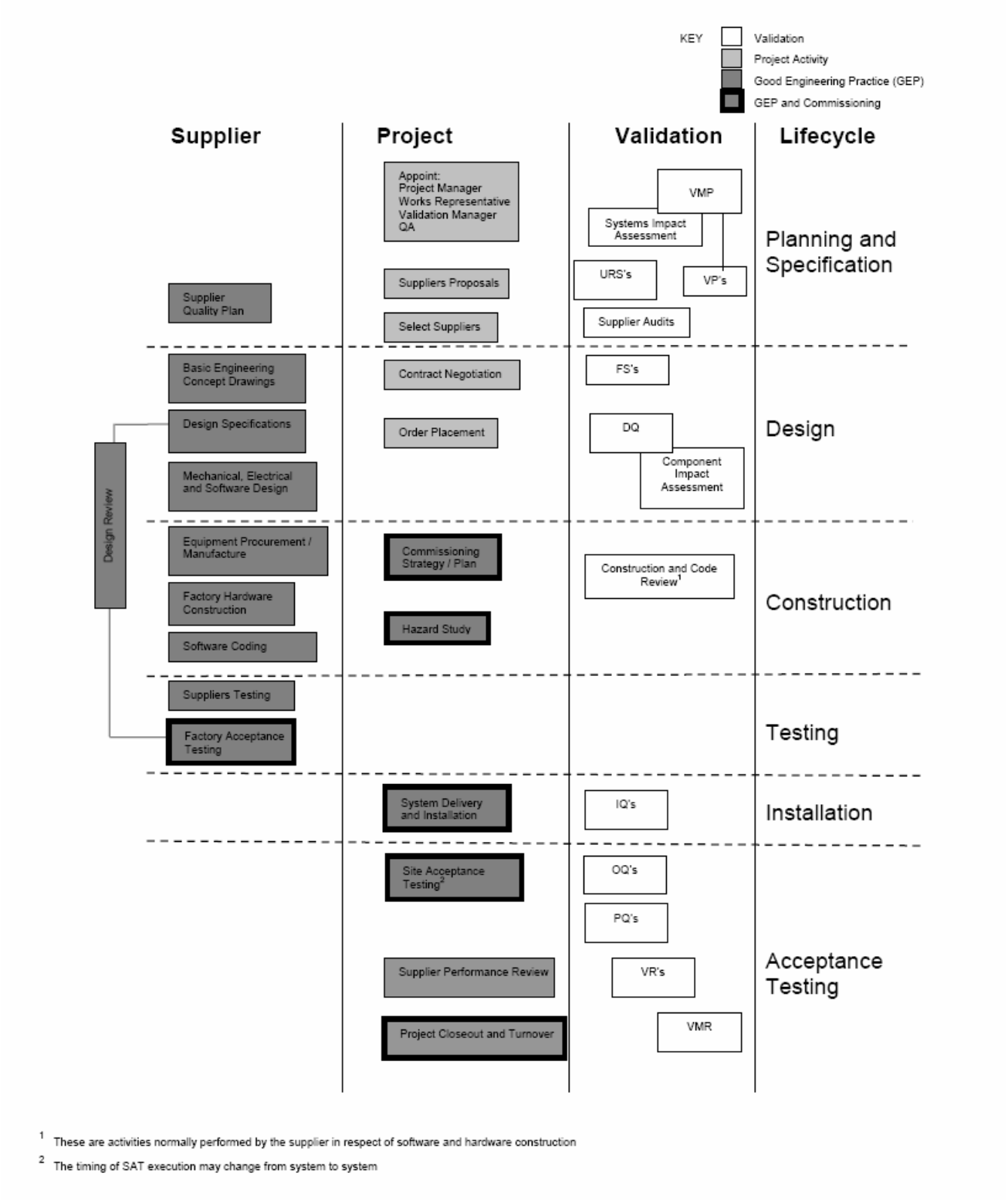
Manual 069

Section 5.2.1

Figure: Examples of Systems showing Spectrum of Impact ISPE Baseline Pharmaceutical Guide, Volume 5 – Commissioning and Qualification.



6.1 Appendix 1: Validation Life Cycle Model



[1] These are activities normally performed by the supplier in respect of software and hardware construction

[2] The timing of SAT execution may change from system to system

6.2 Appendix 2: Example Commissioning and Qualification Activities

The following list is an example of the possible commissioning and qualification activities to be undertaken:

1.	Design Qualification	DQ
2.	Factory acceptance testing (FAT)	Commissioning
3.	Loop continuity checks	Commissioning
4.	Hazardous area inspections	Commissioning
5.	Equipment and systems inspections	Commissioning and IQ
6.	Functional loop tests	Commissioning and OQ
7.	Trip and alarm tests	Commissioning and OQ
8.	Instrument calibration	Commissioning and IQ
9.	Equipment IQ	IQ
10.	Site acceptance testing (SAT)	Commissioning
11.	Control loop tuning/tests	Commissioning and OQ
12.	Phase tests	Commissioning and OQ
13.	Equipment OQ	OQ
14.	Operation tests	Commissioning and OQ
15.	Recipe tests (water trials)	Commissioning and OQ/PQ
16.	Equipment PQ	PQ

NB: Only Direct Impact Systems / Components are subject to qualification.

6.3 Appendix 1: Examples of factors which can determine impact on product quality

A positive answer to any of the questions below will signify a conclusion of direct impact for that system / component. It should be noted that this list of questions is not exhaustive.

1. Does the system/component have direct contact with the product (e.g. air quality)?

2. Does the system/component provide an ingredient or component to the process (e.g. raw material, USP water)?

3. Does the system/component produce data, which is used to accept or reject product (e.g. electronic batch record system, critical process parameter chart recorder)?

4. Does the system/component produce control or manipulate the process in such a way as to affect product quality without independent verification?

   a) Does the normal operation or control of the system/component have a direct effect on product quality?

   b) Does failure or alarm of the system/component have a direct effect on product quality or efficacy?

5. Does the system/component have a direct impact on product purity, safety, efficacy, identity or the measurement or monitoring of these attributes?

6. Is the system/component used in cleaning or sterilizing (e.g. clean steam)?

7. Is the system/component the official archive or record of cGMP related data (e.g. production, training, change control)?

8. Is the system/component used for product complaints, returned goods, product release or recall, or product history?

9. Does the system/component control stock information, stock tracing, stock status, location or shelf life?

10. Does the system/component impact or affect reconciliation, partial use of components or split lots?

11. Does the system/component send GMP data to any other validated computer system?

12. Does the system/component impact or affect coding of raw materials, formulated or packaging components (e.g. label identification)?

13. Is the system/component used in analytical tests associated with a product specification, analytical method or compendia?

14. Can the system/component have a direct impact on product quality in any other way?