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Facilities, Utilities, and Equipment: GMP-Critical vs. Business-Critical

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Within the complex facilities, utilities, and equipment (F/E/U) in a manufacturing plant, a line in the sand needs to be drawn between GMP-critical and business-critical. While the **process for identification has been discussed before**, the following are the differences between a GMP-critical and business-critical F/E/U, including the respective change management, taken from a Jorge Cordero presentation given at IVT's **Validation Week** Canada.

GMP-Critical

GMP-critical F/E/U have a direct impact on the safety, identify, potency-strength, quality, or purity of the product. This can, in part, be determined by following the questions outlined at the **beginning phase** of identifying a GMP-project. Furthermore, GMP-critical F/E/U will directly impact regulatory aspects of the manufacturing process; this includes activities such as labeling, and evaluation, generation, archiving, and reporting data that is used for product release. GMP-critical F/E/U maintain, control, and monitor environmental conditions to preserve product quality. They are also used to clean, sanitize, or sterilize to preserve product quality. Some examples of GMP-critical F/E/U include bottle/cap molding machines, filtered compressed air, ISO 5 cleanrooms, and inspection systems.

Business-Critical

Business-critical F/E/U are those elements that affect the ability to manufacture and operate efficiently; such as boilers, plant steam, compressed air; or elements that affect customer satisfaction; such as cosmetic defects, failures in deliver on time, and missing promotional material. They can also include systems that evaluate and monitor operation efficiencies as well as equipment that helps improve operation efficiencies.

Business-critical F/E/U must comply with good engineering practices (GEPs). This requires:

- Fitness to purpose, reliability, cost effectiveness.
- A design following industry guidance and statutory requirements.
- Consideration GMP, Environmental Safety & Health, ergonomic, operational, and maintenance requirements.
- Proof of professional and competent design, construction, installation testing, and commissioning.
- Appropriate documentation such as design concepts, as build drawings, manuals, certifications, maintenance instructions, and test records.

Change Management

Regarding change management, any change to a GMP-critical F/E/U should be managed under the quality change control system and should be evaluated by a multidisciplinary team. A change description, justification, risk evaluation, change plan, and pre/post-approval should be included. It should follow the applicable project lifecycle, and qualification shall be performed based on criticality of the F/E/U.

For business-critical change management, new F/E/U shall be evaluated and approved by engineering, operations, process excellence, quality, and finance, as applicable. Any change will have to comply with GEP.
