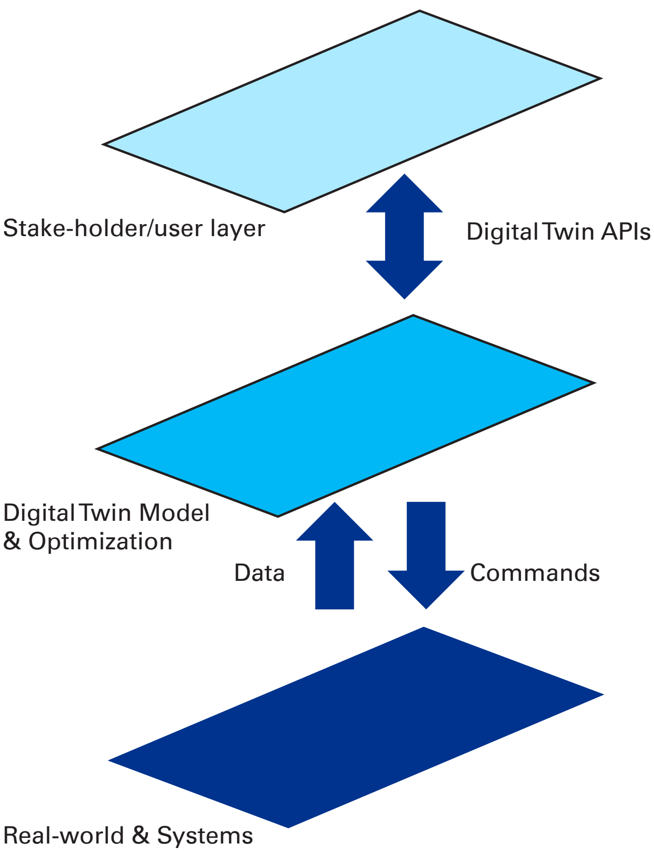
In-the-loop Digital Twins for Life Science: Key Considerations

Background

As discussed in the prior blog, a digital twin can be thought of as a realistic digital representation of physical thing (e.g., living or inanimate, molecule, device), design (i.e., prototype design), system (manufacturing line or facility), or process (e.g., medical devices complaints intake, clinical trials operational management). Typically, a digital twin also includes a digital model (simulation) of the source's process and dynamics that enable it to predict how it would respond in various potential situations/scenarios.

Anatomy of a Digital Twin



Digital twins can be used to provide information and insights on **what happened, what is happening,** or **what will happen** to the system or asset being twinned. The rapid growth, scale, and sophistication of digital twins has been driven by the ubiquitous availability of cloud-computing providing the necessary computing power, advanced artificial intelligence (AI) techniques for process step predictions, process orchestration, and large-scale data integration/Internet of Things (IoT) from key life science enterprise sources that are becoming more mainstream every day.

An in-the-loop digital twin is defined as a digital twin that is continuously tracking the current state of the system being twinned (e.g., **what is happening**) through data that is being refreshed from sensors and systems that capture and reflect the changes in the system as processes execute. As the digital twin takes in data in an ongoing manner through IoT (real-time) and other slower sources (in-time), it provides an intuitive overall view to digital twin users. This view allows users to see the overall current status of the system in terms of key parameter value, location of assets, and process progress (such as in a control tower or 3D representation of the physical manufacturing line, or facility being twinned). Digital twins also typically provide for recording and playback of the twinned system's past behavior (e.g., **what happened**) for review, diagnosis, and training purposes.

The key value of an **in-the loop digital twin** occurs when the twin has a forward-looking simulation capability. This allows a "**digital fast-forward** to a "**what will happen**" view. This view supports the early identification of potential short-term and longer-term issues and creates the option to manually develop and evaluate proactive response/mitigation actions scenarios that can be selected before the point of no return is reached. Furthermore, for more complex scenarios, AI and optimization systems can be integrated with the simulation to intelligently generate and test multiple potential mitigation actions and provide a set of options to decision makers along with likely outcomes for their decision support.

Of course, an in-the-loop digital twin is a complex undertaking requiring robust IoT and operational data management intake, integration, and governance, occurring at a pace that can keep the digital twin up sufficiently synchronized with the system being twinned.

Equally important is the fidelity of the simulation model being used for prediction and its associated calibration and validation. For example, no simulation has perfect fidelity in terms of forward simulation. Generally, the farther out in time the simulation projects forward, the greater the divergence from what it predicts vs. what the actual system state will be, and it is important to characterize this range. Therefore, it is necessary before operationalizing a digital twin, especially in the context of systems, assets, and processes falling under GxP and clinical/regulatory controls, to undertake careful planning, piloting, and validation of the proposed digital twin.

This is similar to what would be required of any GxP software or AI/advanced algorithm, depending on risk classification. However, short of full integration/operationalization, careful thought about how the digital twin will be leveraged in the context of operations and training can potentially lessen the validation burden by reducing the risk classification.

At KPMG we have an experienced team with a deep understanding of the practical applications and technical principles of how to impactfully apply digital twins to life science enterprises. We also can provide expertise around regulatory aspects of applying Digital Twins in a compliant manner within GxP processes. KPMG welcomes the opportunity to support your strategy, selection, and operationalization of digital twins.

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