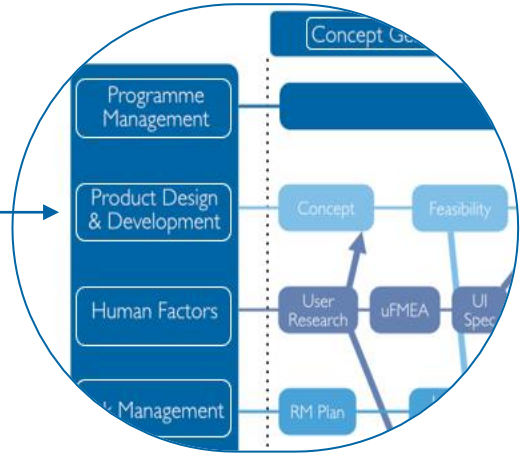
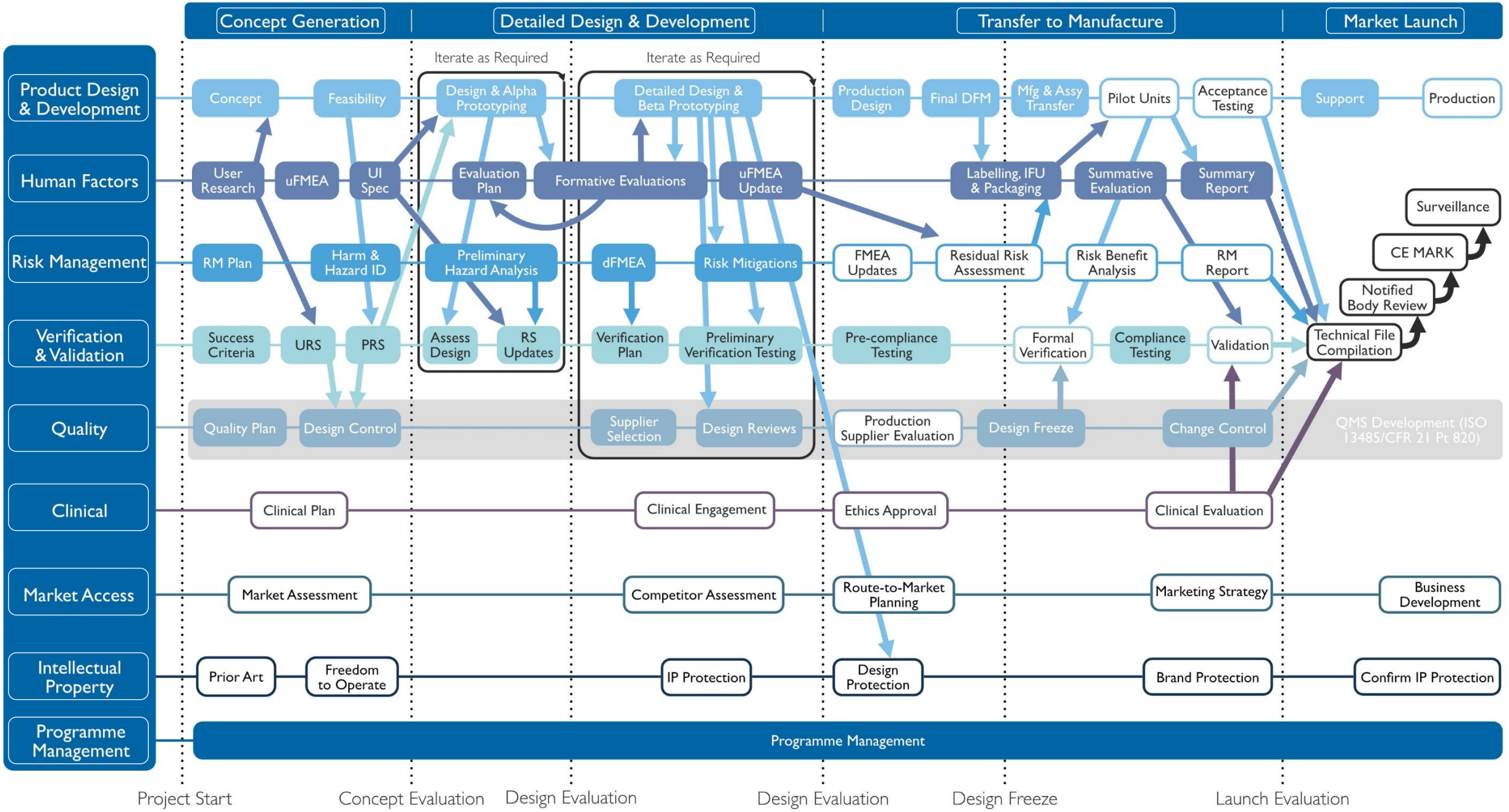
Product Design & Development Plan – Interactive Guide

How to Use This Document

- The diagram on the following pages shows the key stages (along the top), and key processes (down the lefthand side) involved with a typical medical device design project
- The arrows represent the interactions between the various processes
- Click on the **white heading boxes** to find out more about each process
- Press  at the bottom of the page to return to the full process diagram
- Diagram Key
  - Colour-fill boxes: services offered by eg technology
  - White-fill boxes: services to be provided externally – eg can recommend third parties if requested

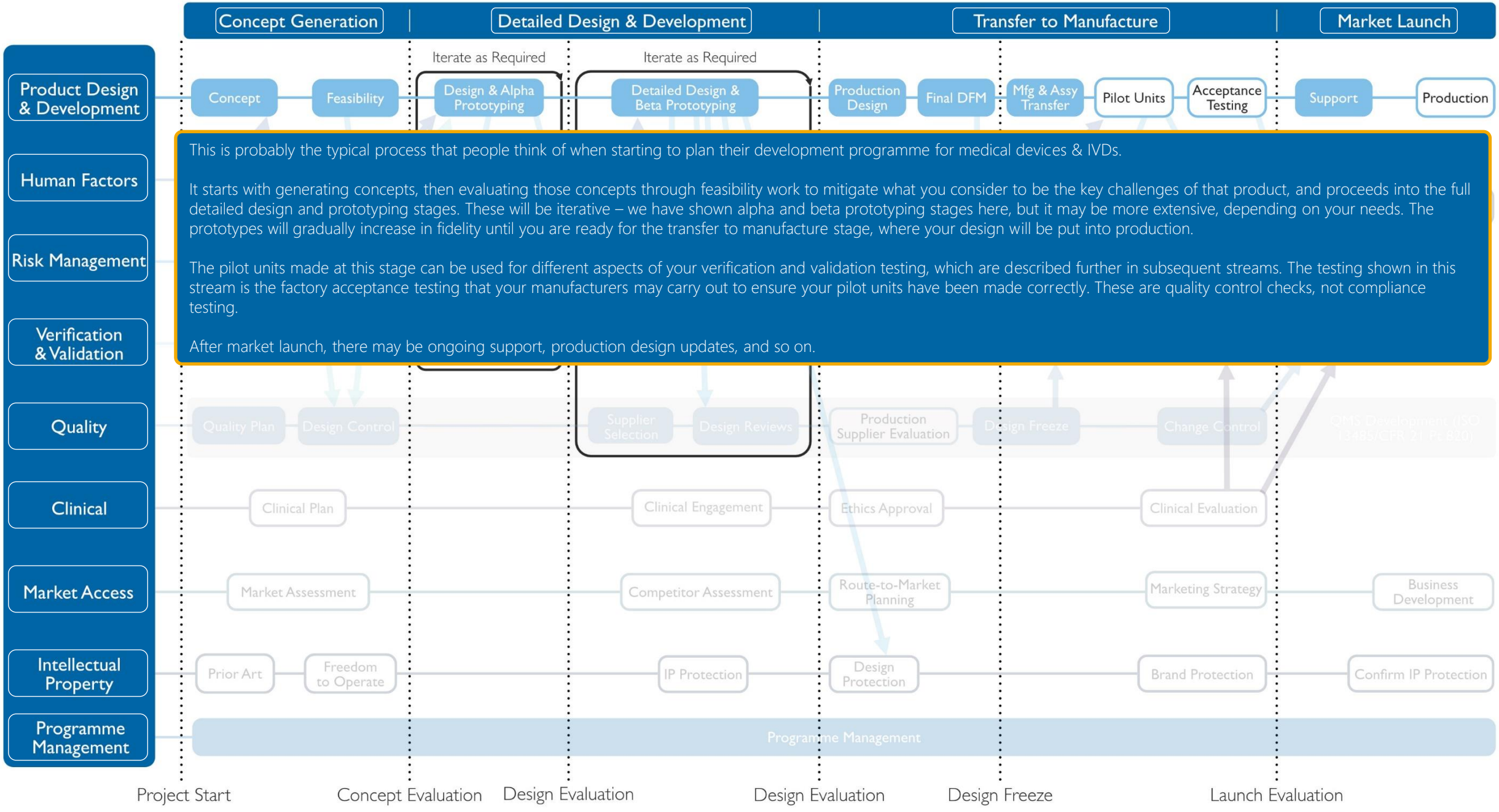


Please note this document is intended to be used as a framework only, and each project should be individually tailored and adapted.



KEY: 3rd Party Process | eg technology Process

eg technology



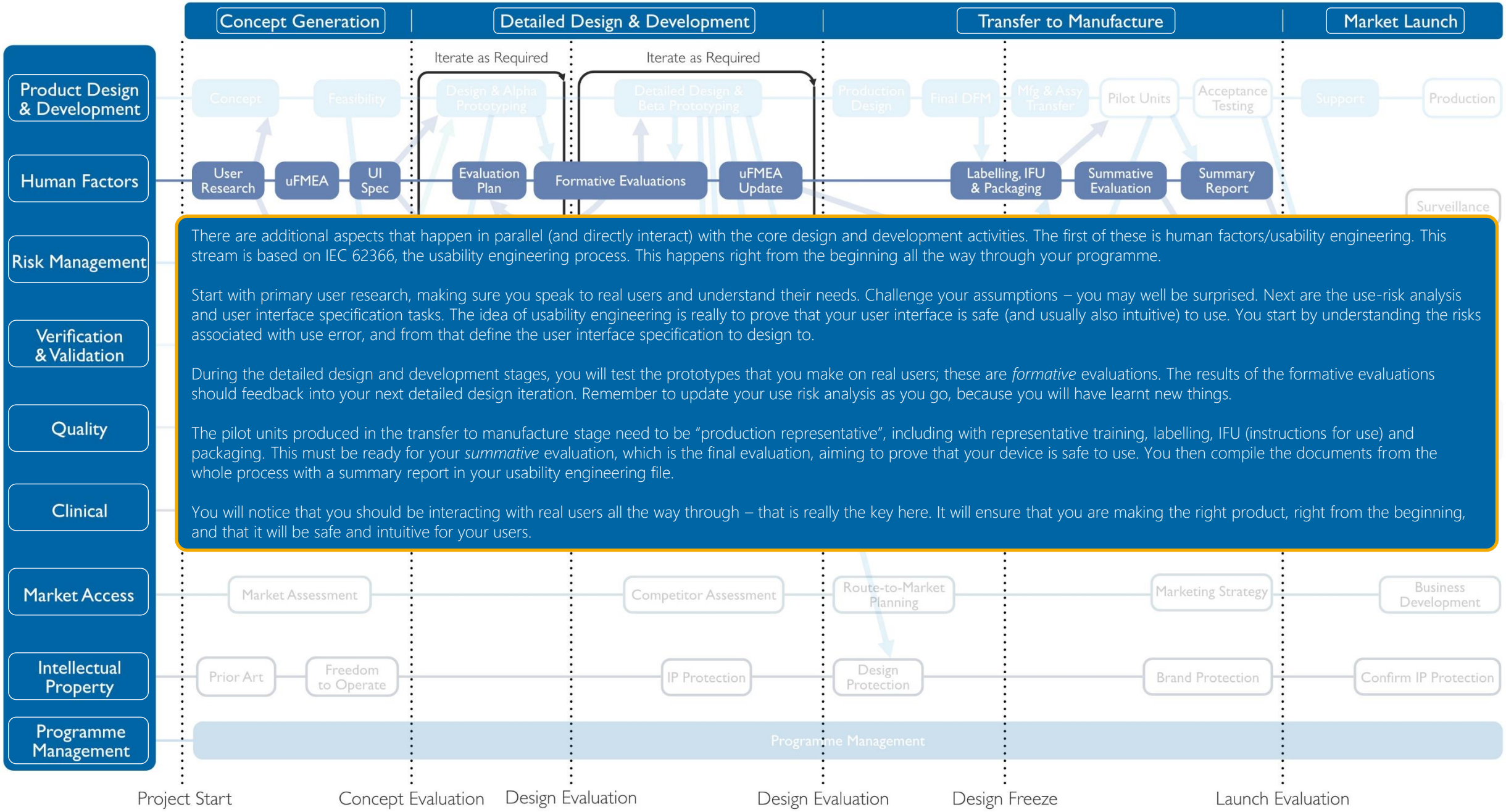
This is probably the typical process that people think of when starting to plan their development programme for medical devices & IVDs.

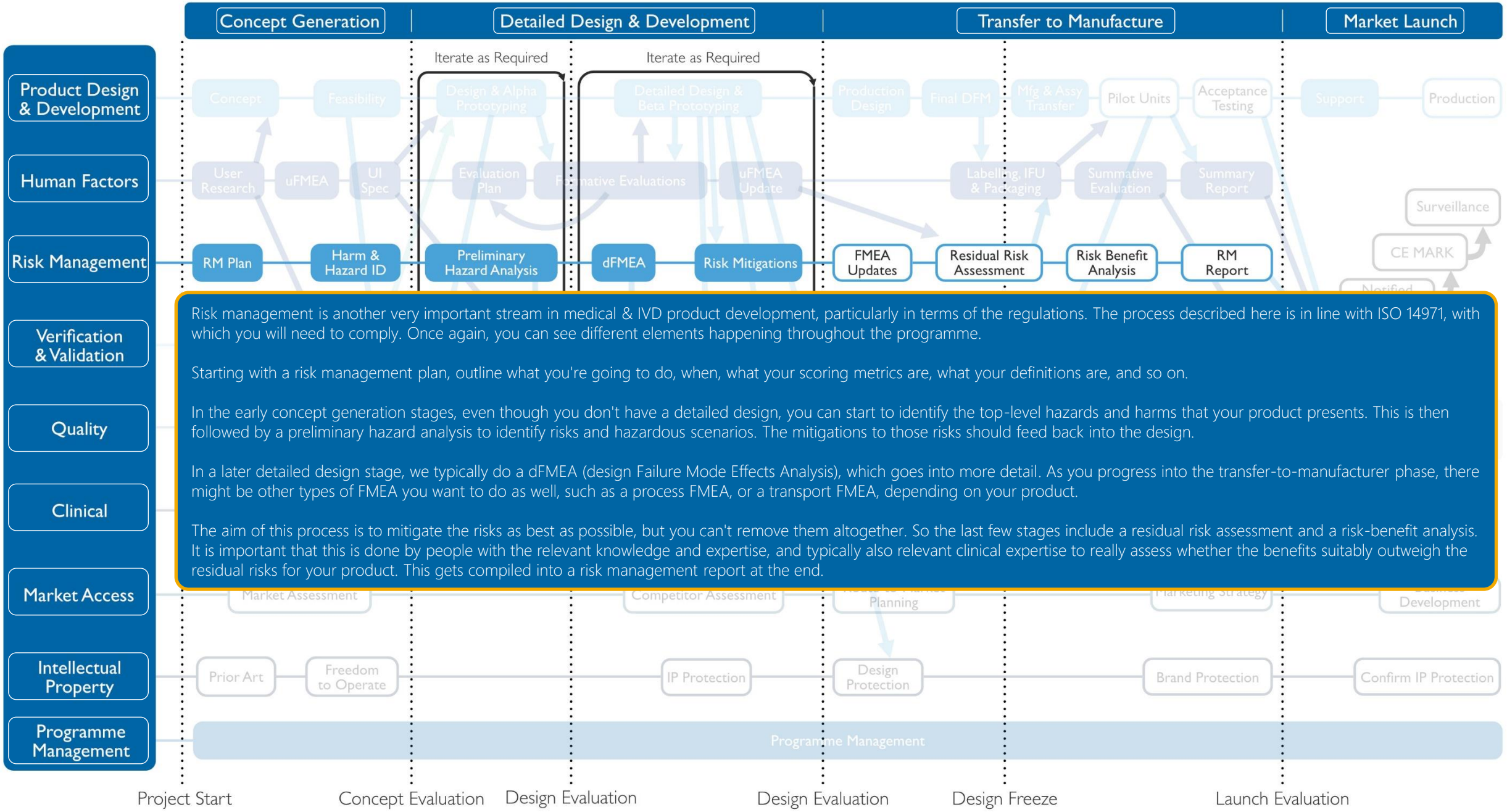
It starts with generating concepts, then evaluating those concepts through feasibility work to mitigate what you consider to be the key challenges of that product, and proceeds into the full detailed design and prototyping stages. These will be iterative – we have shown alpha and beta prototyping stages here, but it may be more extensive, depending on your needs. The prototypes will gradually increase in fidelity until you are ready for the transfer to manufacture stage, where your design will be put into production.

The pilot units made at this stage can be used for different aspects of your verification and validation testing, which are described further in subsequent streams. The testing shown in this stream is the factory acceptance testing that your manufacturers may carry out to ensure your pilot units have been made correctly. These are quality control checks, not compliance testing.

After market launch, there may be ongoing support, production design updates, and so on.

KEY 3rd Party Process | eg technology Process





Risk management is another very important stream in medical & IVD product development, particularly in terms of the regulations. The process described here is in line with ISO 14971, with which you will need to comply. Once again, you can see different elements happening throughout the programme.

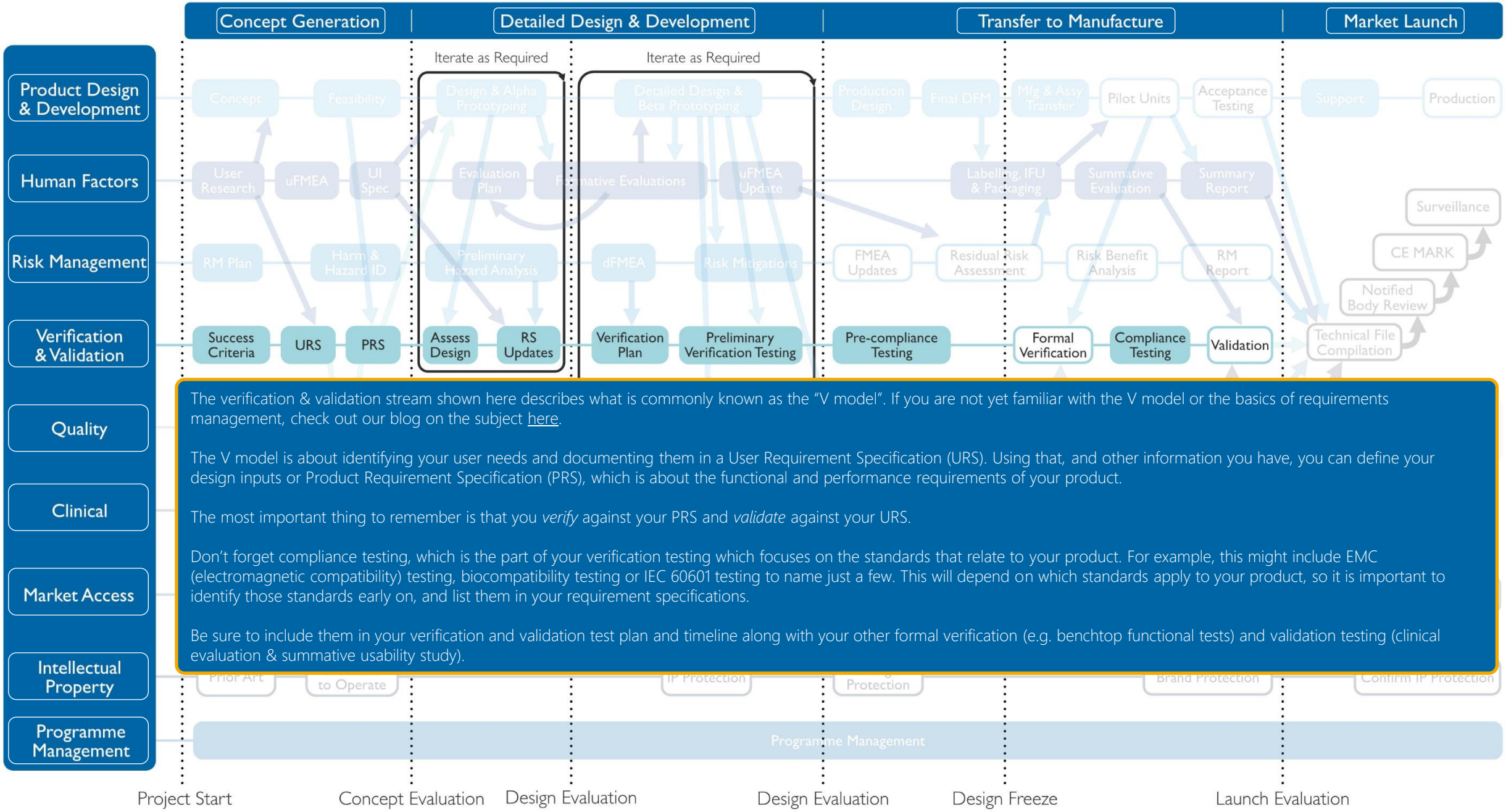
Starting with a risk management plan, outline what you're going to do, when, what your scoring metrics are, what your definitions are, and so on.

In the early concept generation stages, even though you don't have a detailed design, you can start to identify the top-level hazards and harms that your product presents. This is then followed by a preliminary hazard analysis to identify risks and hazardous scenarios. The mitigations to those risks should feed back into the design.

In a later detailed design stage, we typically do a dFMEA (design Failure Mode Effects Analysis), which goes into more detail. As you progress into the transfer-to-manufacturer phase, there might be other types of FMEA you want to do as well, such as a process FMEA, or a transport FMEA, depending on your product.

The aim of this process is to mitigate the risks as best as possible, but you can't remove them altogether. So the last few stages include a residual risk assessment and a risk-benefit analysis. It is important that this is done by people with the relevant knowledge and expertise, and typically also relevant clinical expertise to really assess whether the benefits suitably outweigh the residual risks for your product. This gets compiled into a risk management report at the end.

KEY 3rd Party Process | eg technology Process



The verification & validation stream shown here describes what is commonly known as the "V model". If you are not yet familiar with the V model or the basics of requirements management, check out our blog on the subject here.

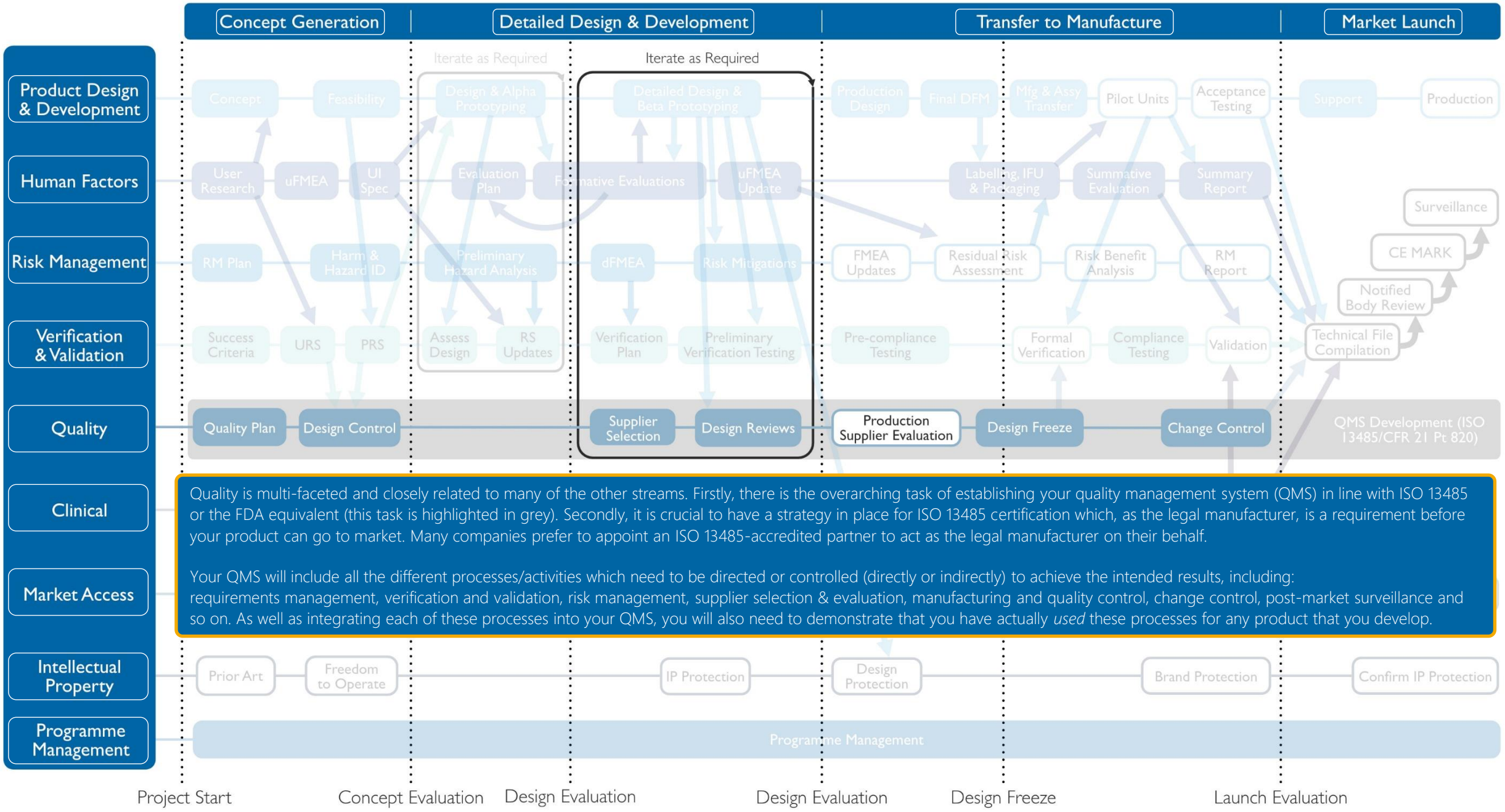
The V model is about identifying your user needs and documenting them in a User Requirement Specification (URS). Using that, and other information you have, you can define your design inputs or Product Requirement Specification (PRS), which is about the functional and performance requirements of your product.

The most important thing to remember is that you *verify* against your PRS and *validate* against your URS.

Don't forget compliance testing, which is the part of your verification testing which focuses on the standards that relate to your product. For example, this might include EMC (electromagnetic compatibility) testing, biocompatibility testing or IEC 60601 testing to name just a few. This will depend on which standards apply to your product, so it is important to identify those standards early on, and list them in your requirement specifications.

Be sure to include them in your verification and validation test plan and timeline along with your other formal verification (e.g. benchtop functional tests) and validation testing (clinical evaluation & summative usability study).

KEY 3rd Party Process | eg technology Process

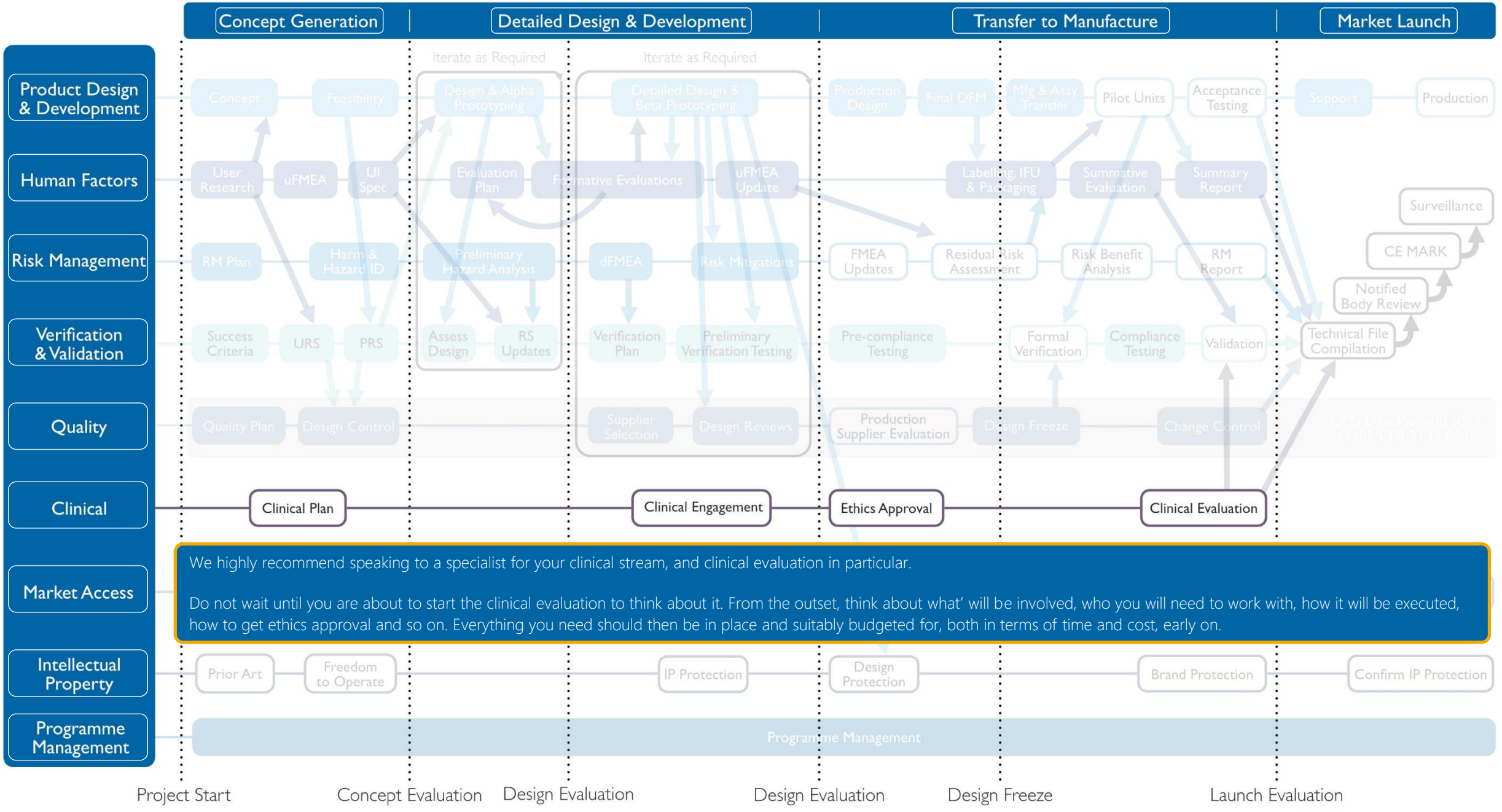


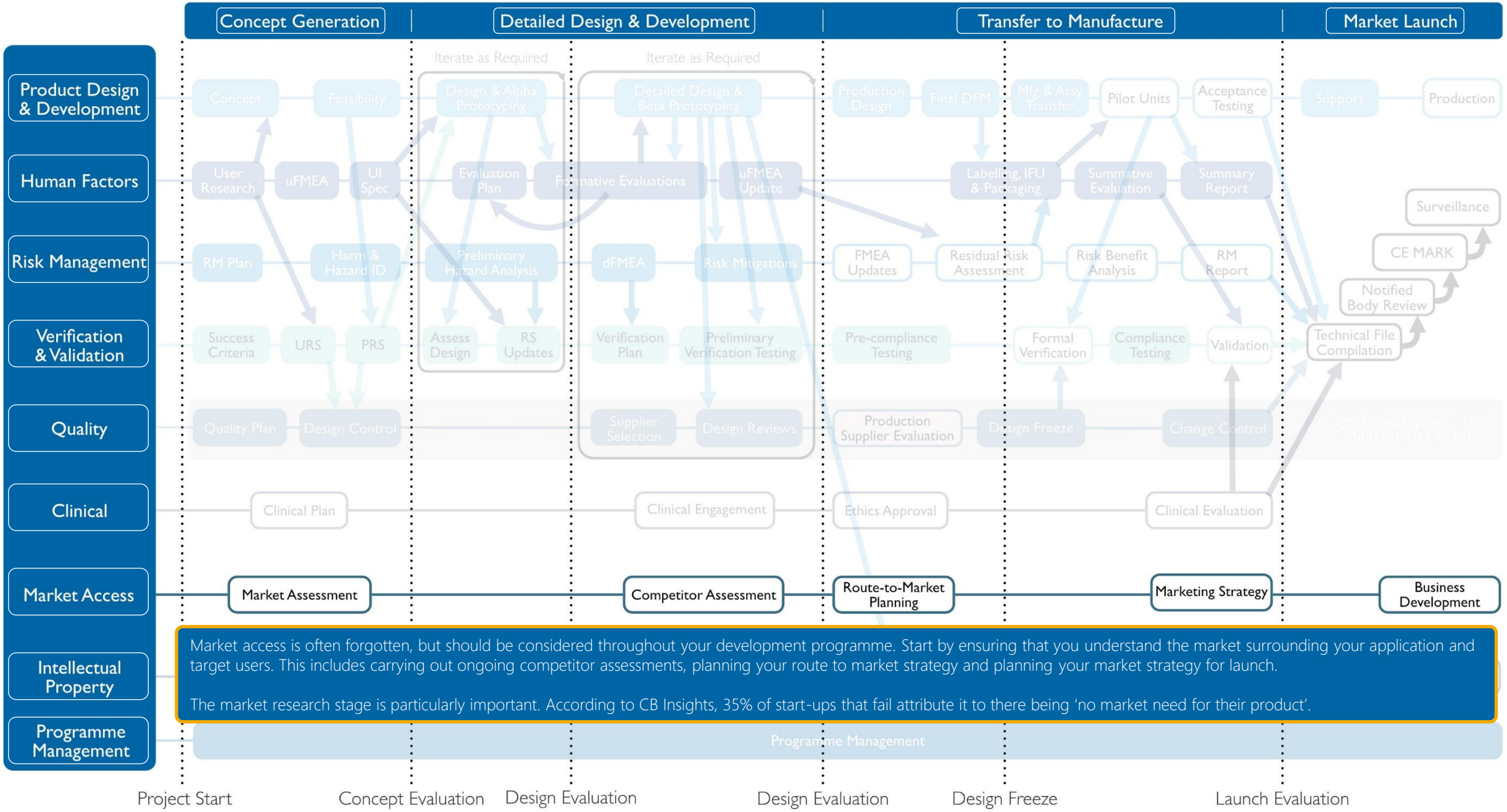
Quality is multi-faceted and closely related to many of the other streams. Firstly, there is the overarching task of establishing your quality management system (QMS) in line with ISO 13485 or the FDA equivalent (this task is highlighted in grey). Secondly, it is crucial to have a strategy in place for ISO 13485 certification which, as the legal manufacturer, is a requirement before your product can go to market. Many companies prefer to appoint an ISO 13485-accredited partner to act as the legal manufacturer on their behalf.

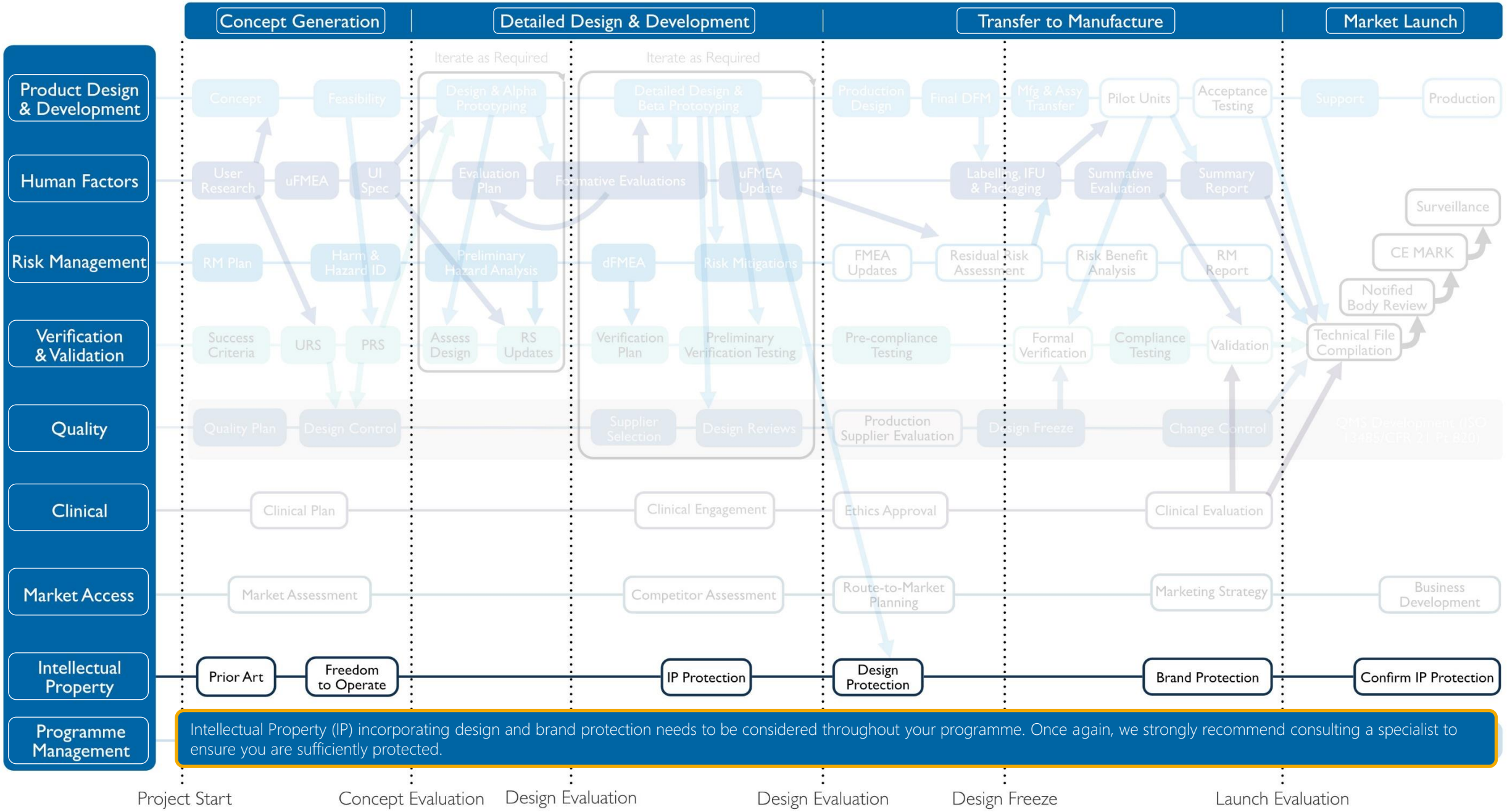
Your QMS will include all the different processes/activities which need to be directed or controlled (directly or indirectly) to achieve the intended results, including: requirements management, verification and validation, risk management, supplier selection & evaluation, manufacturing and quality control, change control, post-market surveillance and so on. As well as integrating each of these processes into your QMS, you will also need to demonstrate that you have actually *used* these processes for any product that you develop.

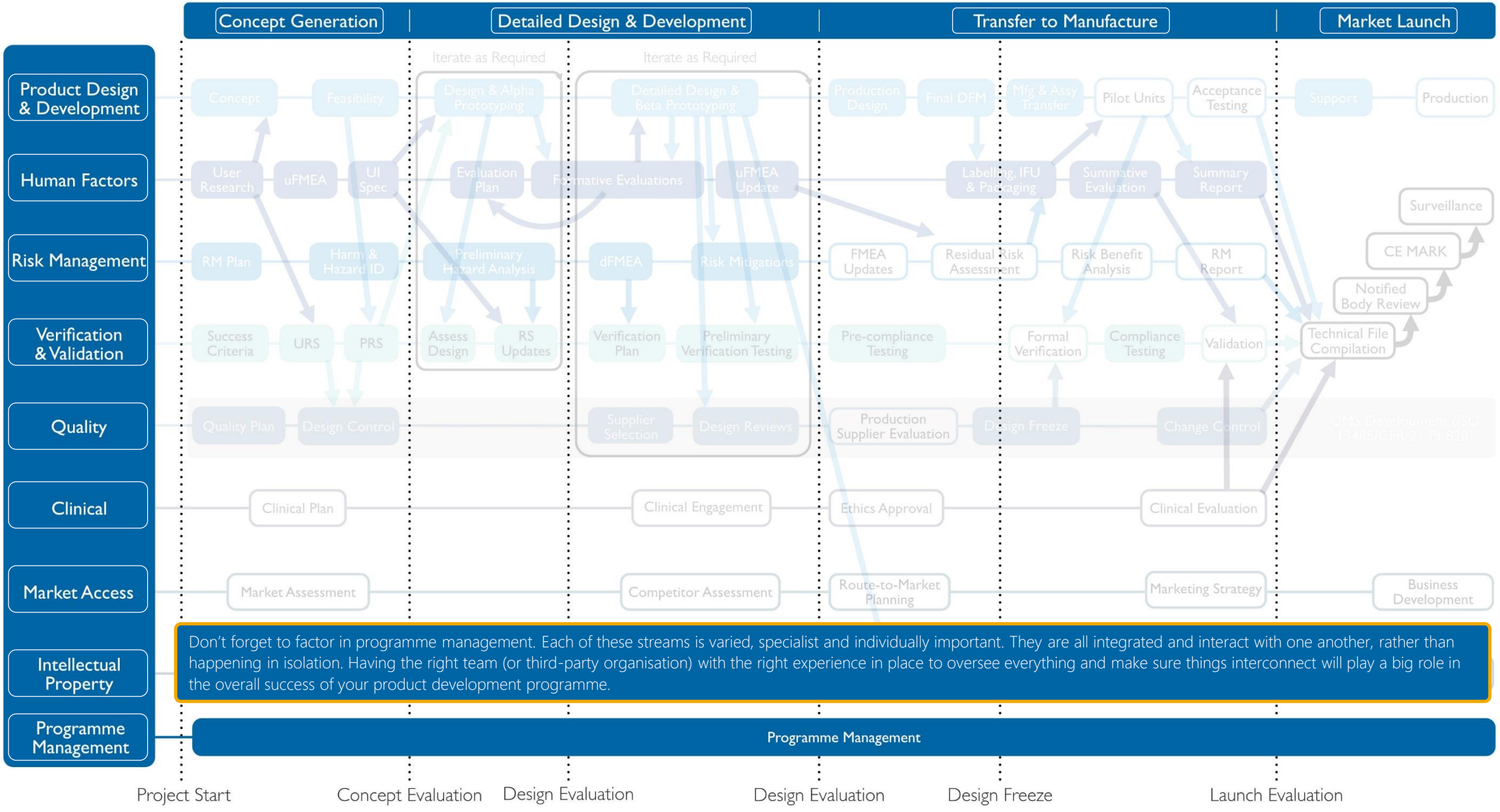
KEY 3rd Party Process | eg technology Process

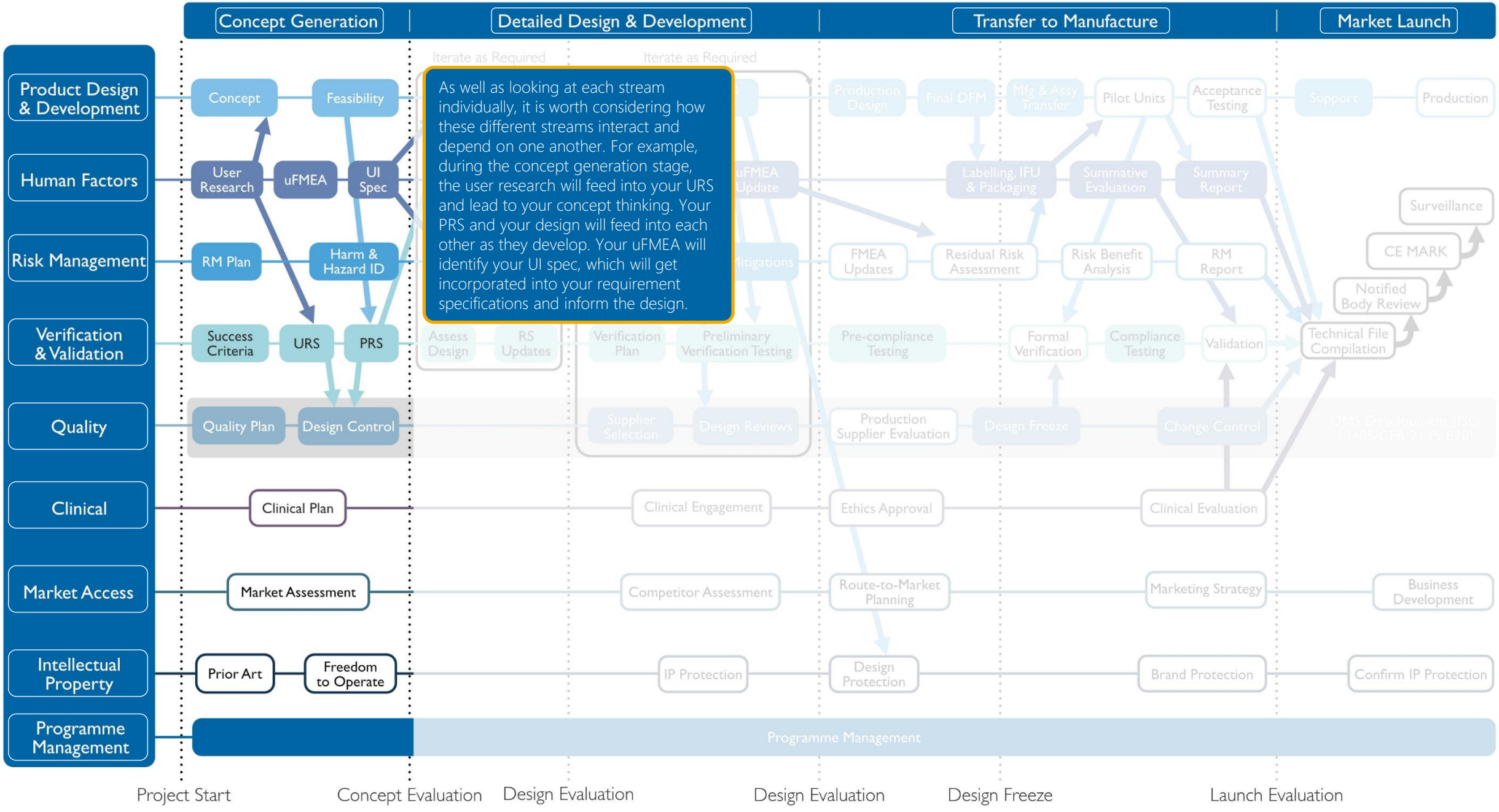
eg technology





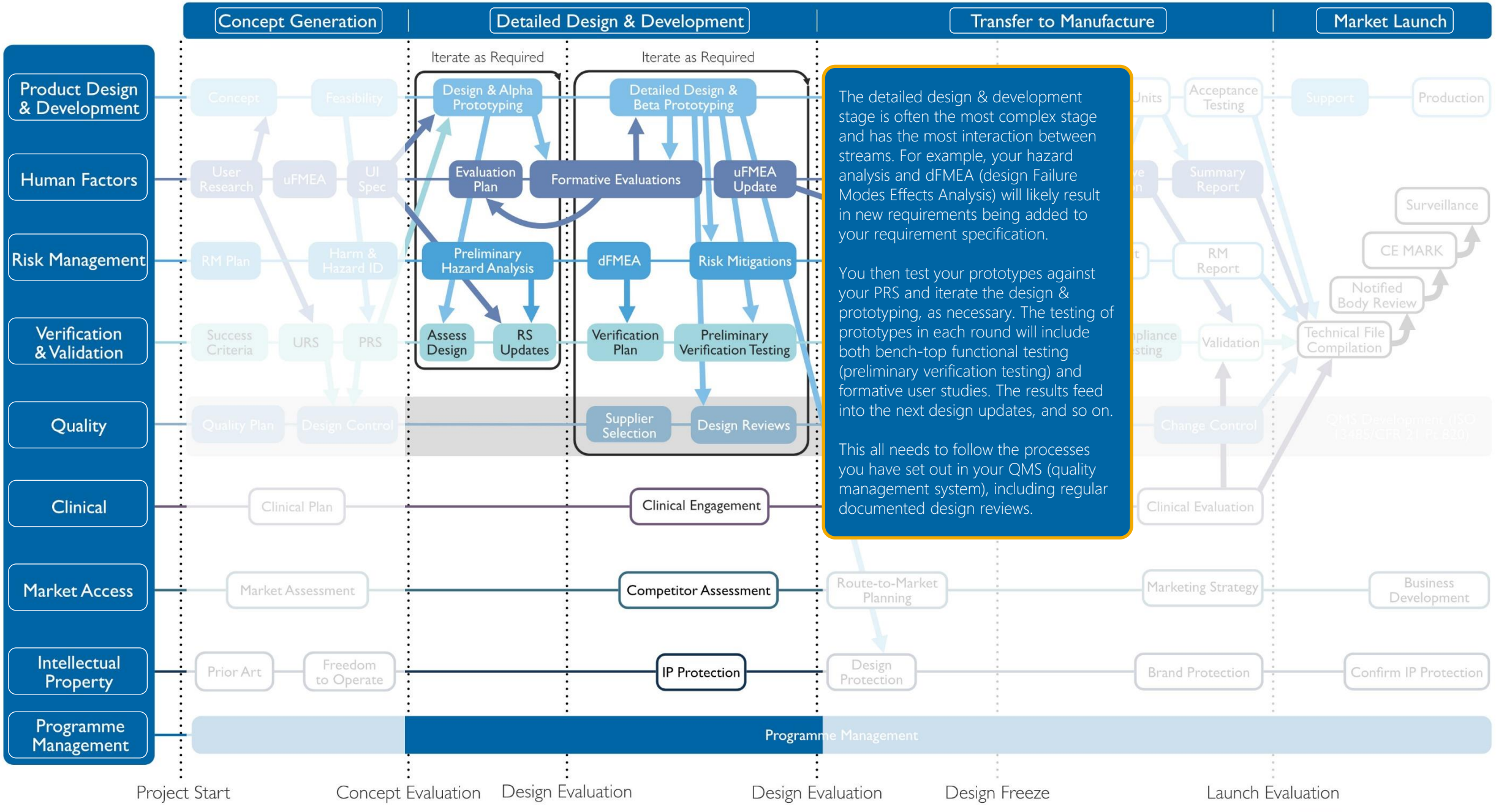






As well as looking at each stream individually, it is worth considering how these different streams interact and depend on one another. For example, during the concept generation stage, the user research will feed into your URS and lead to your concept thinking. Your PRS and your design will feed into each other as they develop. Your uFMEA will identify your UI spec, which will get incorporated into your requirement specifications and inform the design.

KEY: 3rd Party Process | eg technology Process



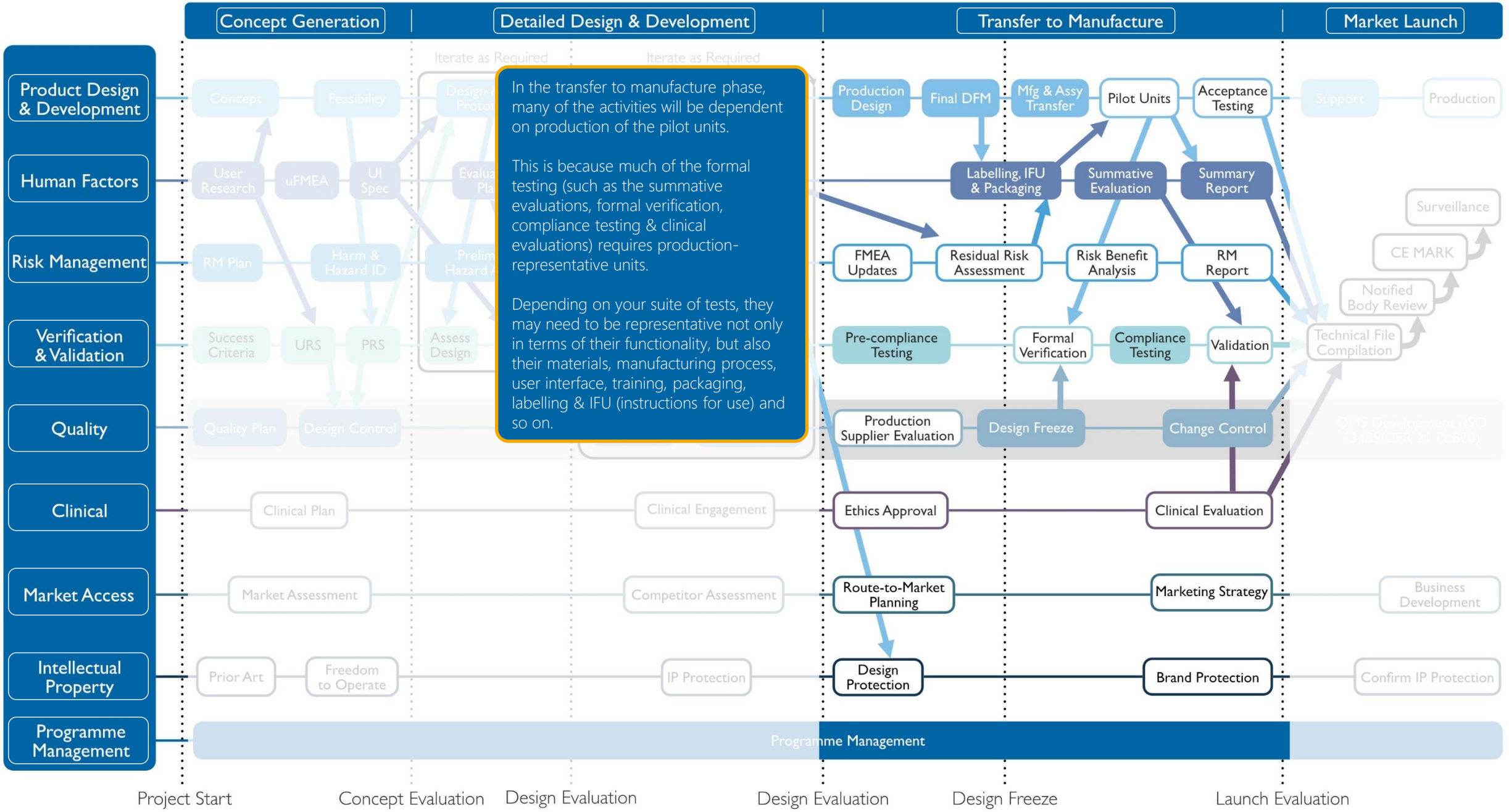
The detailed design & development stage is often the most complex stage and has the most interaction between streams. For example, your hazard analysis and dFMEA (design Failure Modes Effects Analysis) will likely result in new requirements being added to your requirement specification.

You then test your prototypes against your PRS and iterate the design & prototyping, as necessary. The testing of prototypes in each round will include both bench-top functional testing (preliminary verification testing) and formative user studies. The results feed into the next design updates, and so on.

This all needs to follow the processes you have set out in your QMS (quality management system), including regular documented design reviews.

KEY: 3rd Party Process | eg technology Process

eg technology



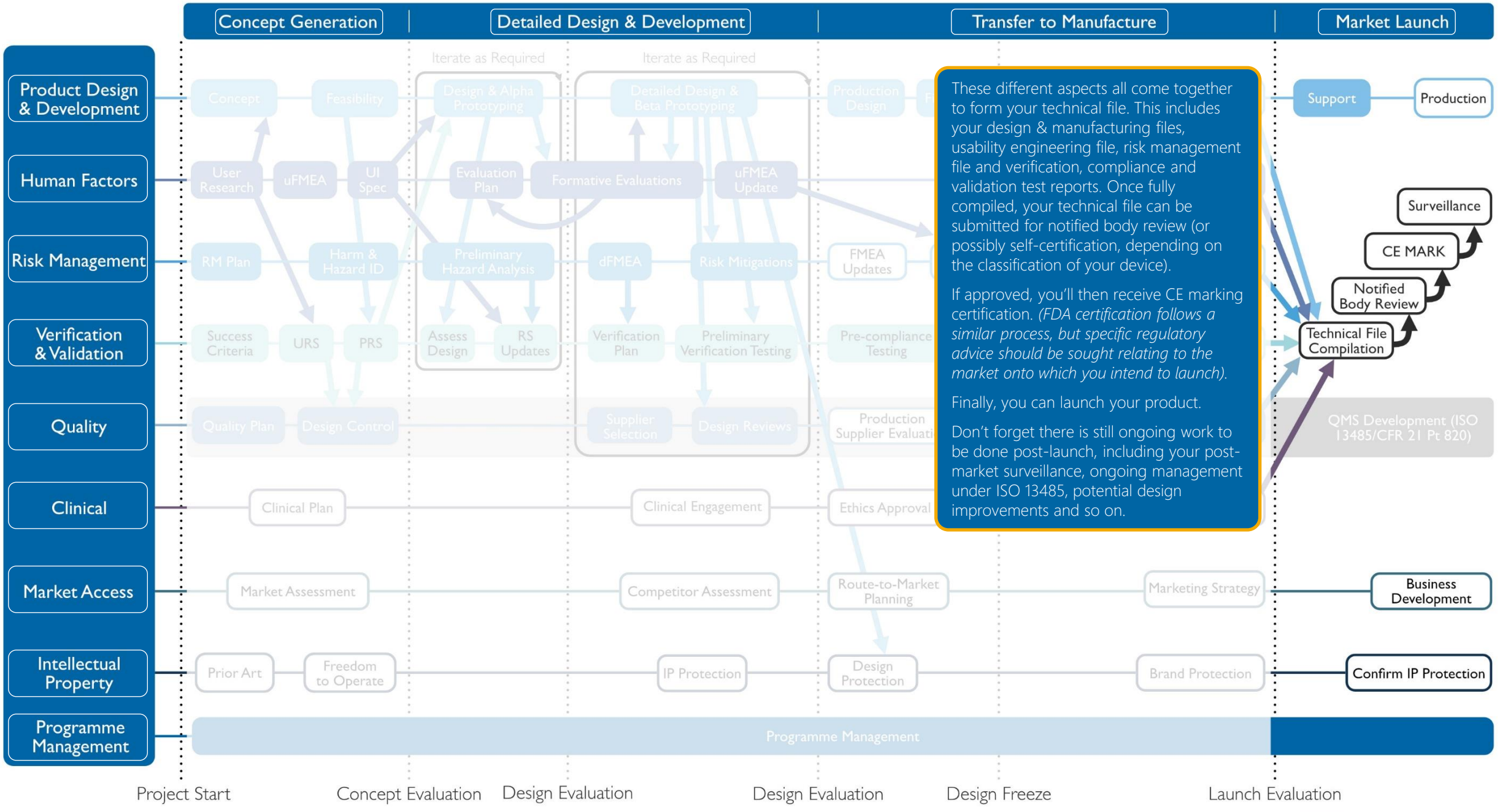
In the transfer to manufacture phase, many of the activities will be dependent on production of the pilot units.

This is because much of the formal testing (such as the summative evaluations, formal verification, compliance testing & clinical evaluations) requires production-representative units.

Depending on your suite of tests, they may need to be representative not only in terms of their functionality, but also their materials, manufacturing process, user interface, training, packaging, labelling & IFU (instructions for use) and so on.

KEY: 3rd Party Process | eg technology Process

eg technology



These different aspects all come together to form your technical file. This includes your design & manufacturing files, usability engineering file, risk management file and verification, compliance and validation test reports. Once fully compiled, your technical file can be submitted for notified body review (or possibly self-certification, depending on the classification of your device).

If approved, you'll then receive CE marking certification. *(FDA certification follows a similar process, but specific regulatory advice should be sought relating to the market onto which you intend to launch).*

Finally, you can launch your product.

Don't forget there is still ongoing work to be done post-launch, including your post-market surveillance, ongoing management under ISO 13485, potential design improvements and so on.

KEY 3rd Party Process | eg technology Process

eg technology

To discuss your product design and development requirements, please book a call with one of our team:

+44 (0) 1223 813184

design@egtechnology.co.uk

www.egtechnology.co.uk