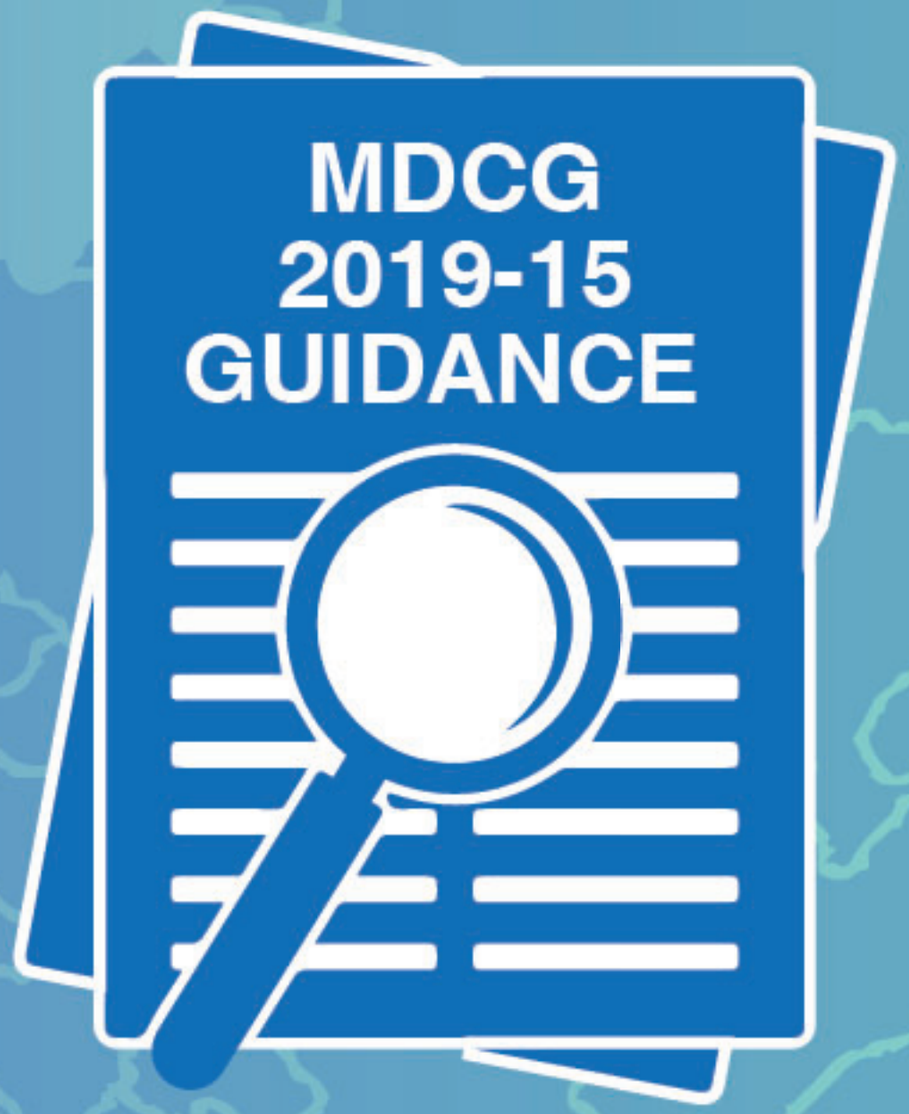
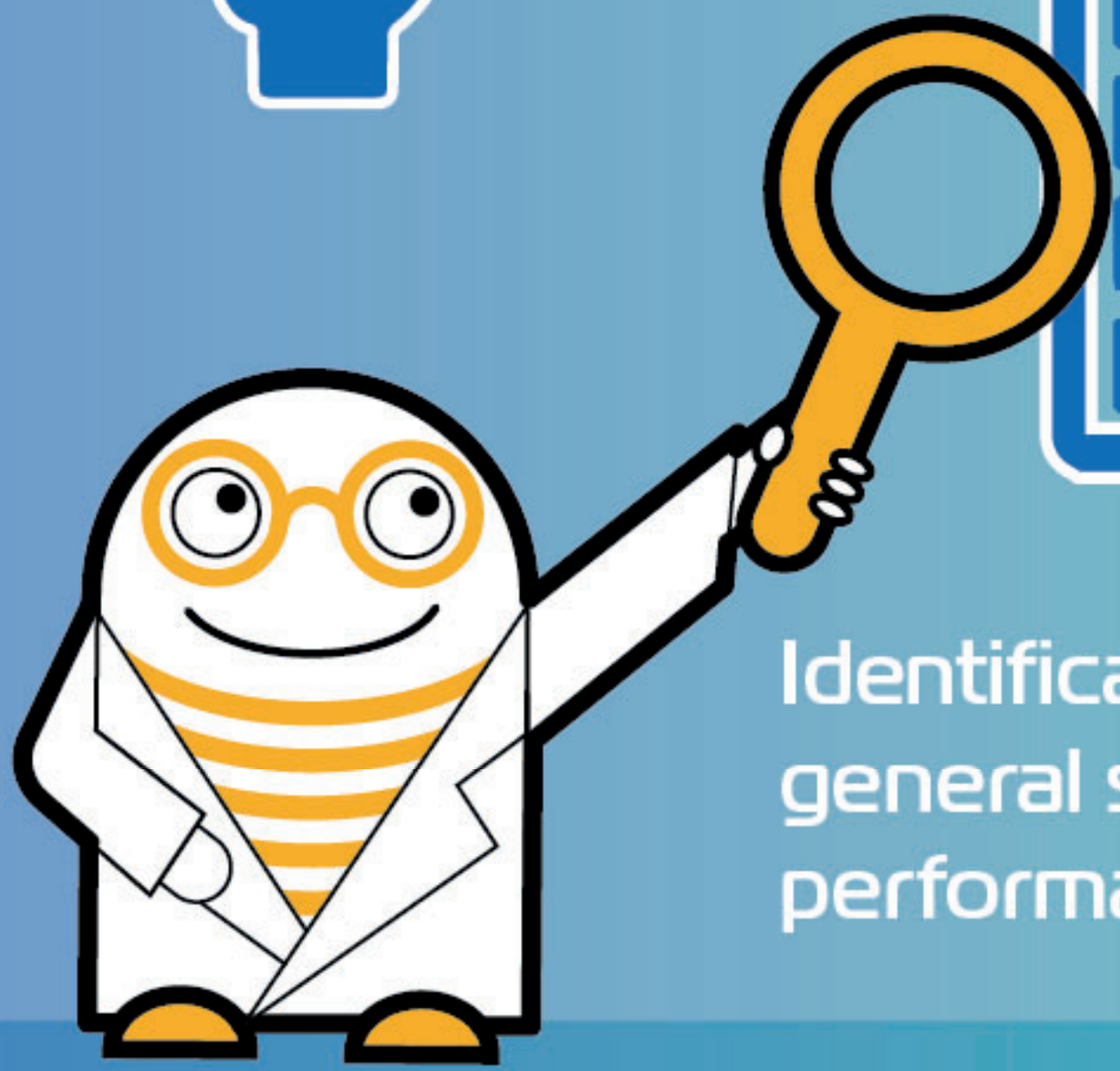
Guidance of the Medical Device Coordination Group for manufacturers of Class I medical devices.

EU MDR Medical Device Regulation



The MDCG recommends the establishement of a quality management system that includes :

A strategy for regulatory compliance,



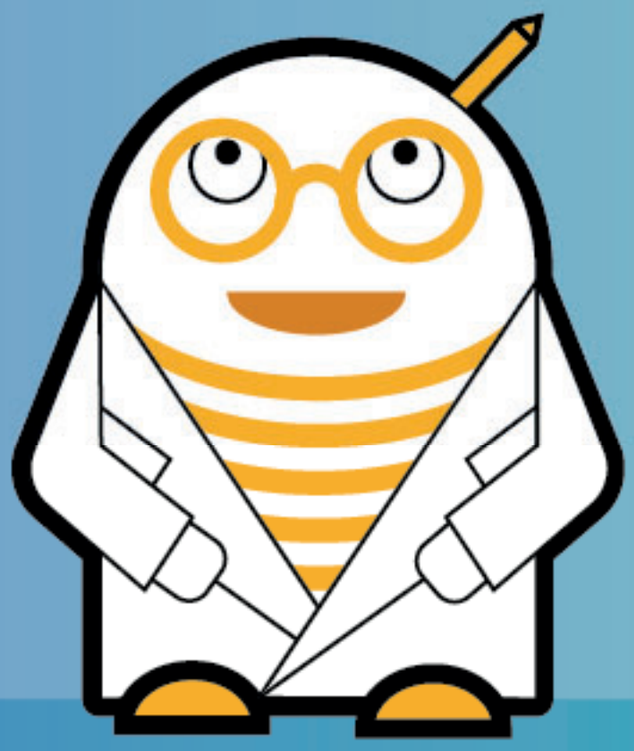
Identification of applicable general safety and performance requirements

The MDCG recommends the establishement of a quality management system that includes :

Resource management

Responsibility of the management

Risk management



The MDCG recommends the establishement of a quality management system that includes :

Clinical evaluation

Product realisation, including planning, design, development, production and service provision

The MDCG recommends the establishement of a quality management system that includes :

Verification of the UDI assignments

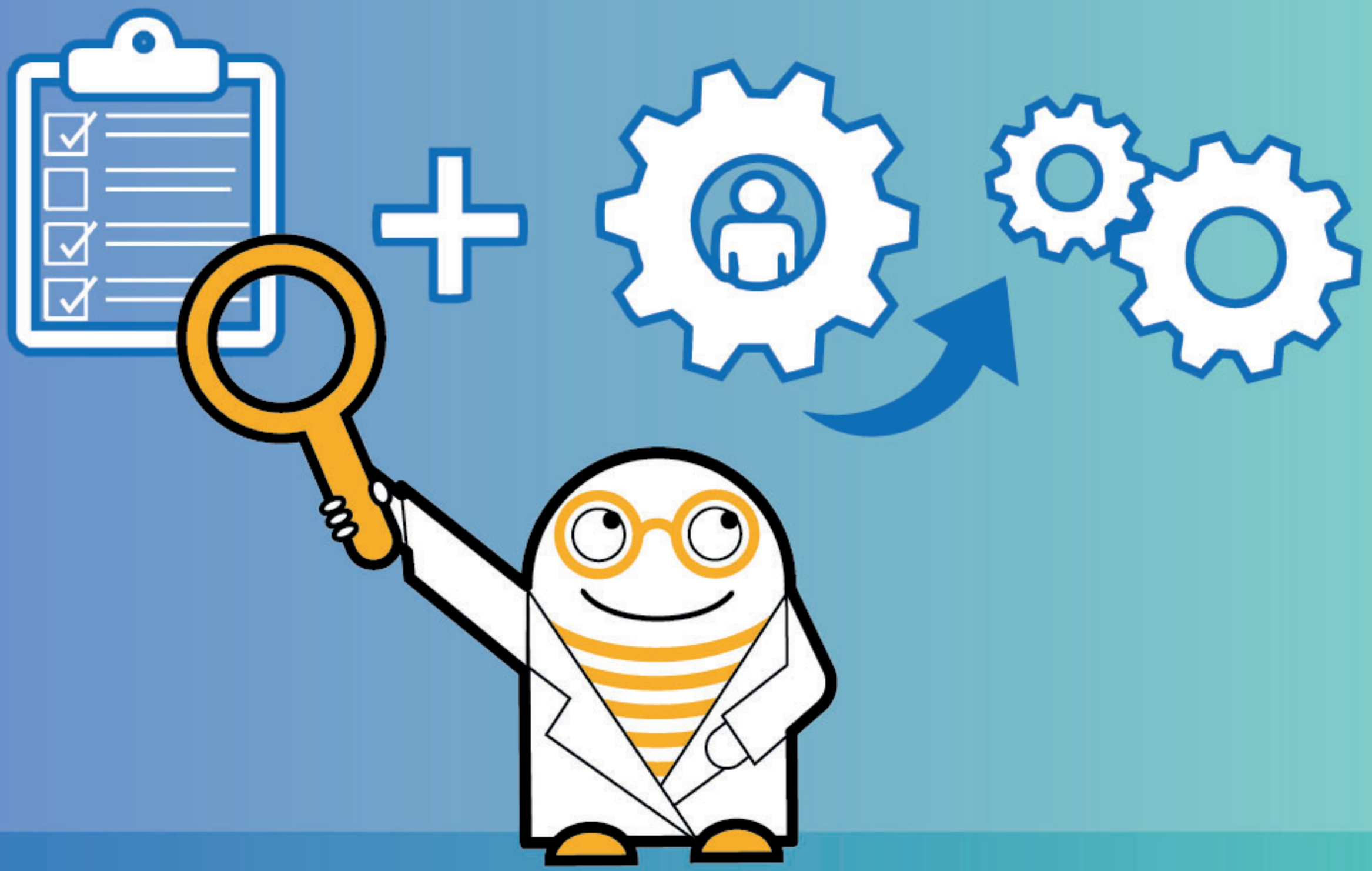
Establishing a post-market surveillance system

The MDCG recommends the establishement of a quality management system that includes :

Handling communication with all stakeholders

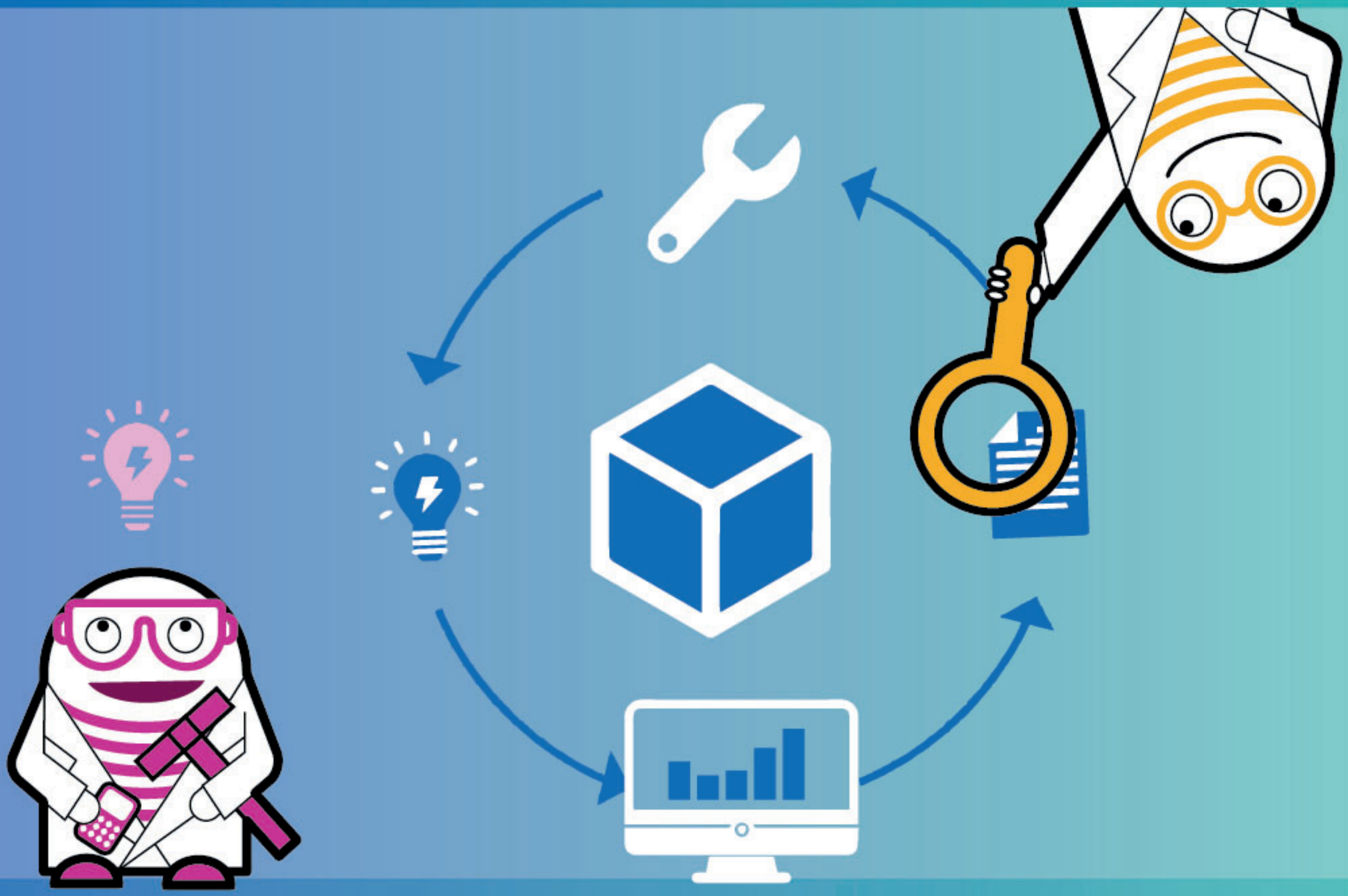
Processes for reporting serious incidents and field safety corrective actions

The MDCG recommends the establishement of a quality management system that includes :



Management of corrective and preventive actions and verification of their effectiveness

The MDCG recommends the establishement of a quality management system that includes :



Processes for monitoring and implementing product improvement.

For more information, contact us.

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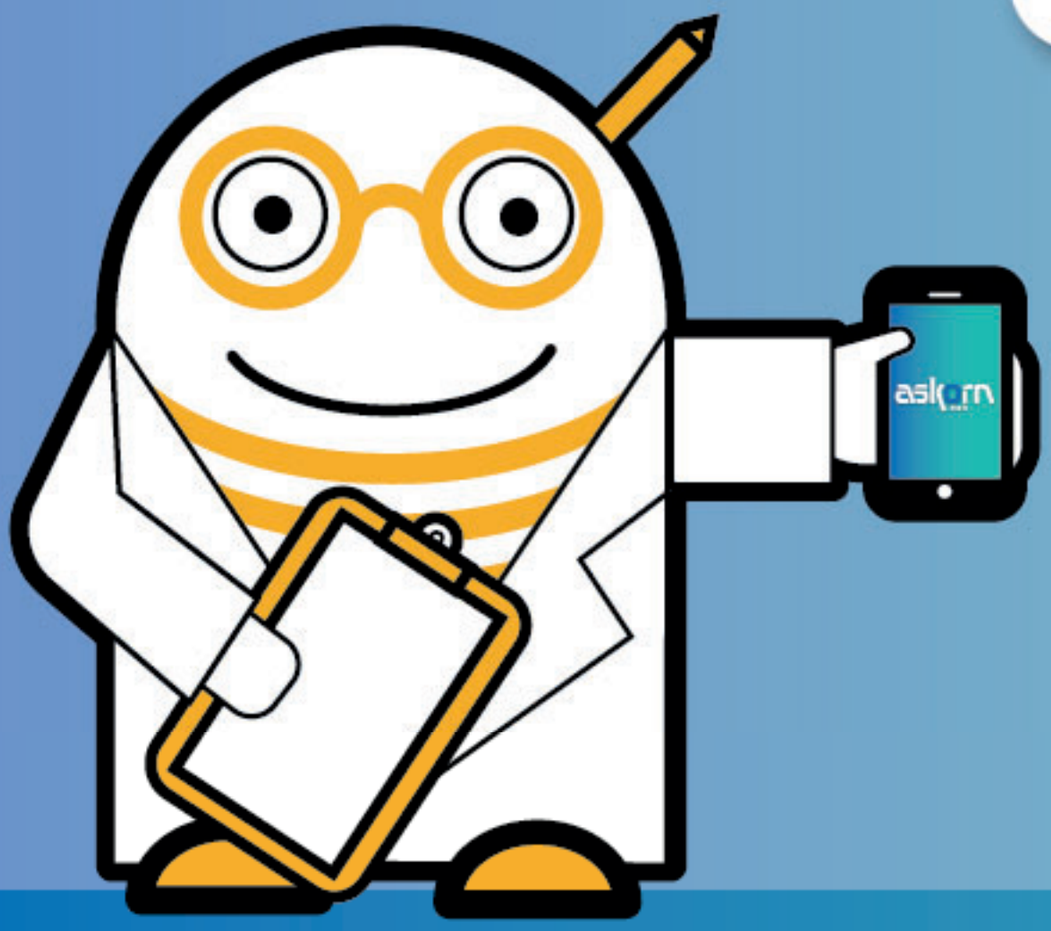

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