FDA'S NEW DRAFT GUIDANCE ON

PREDETERMINED CHANGECONTROL PLANS (PCCPS) FOR MEDICAL DEVICES

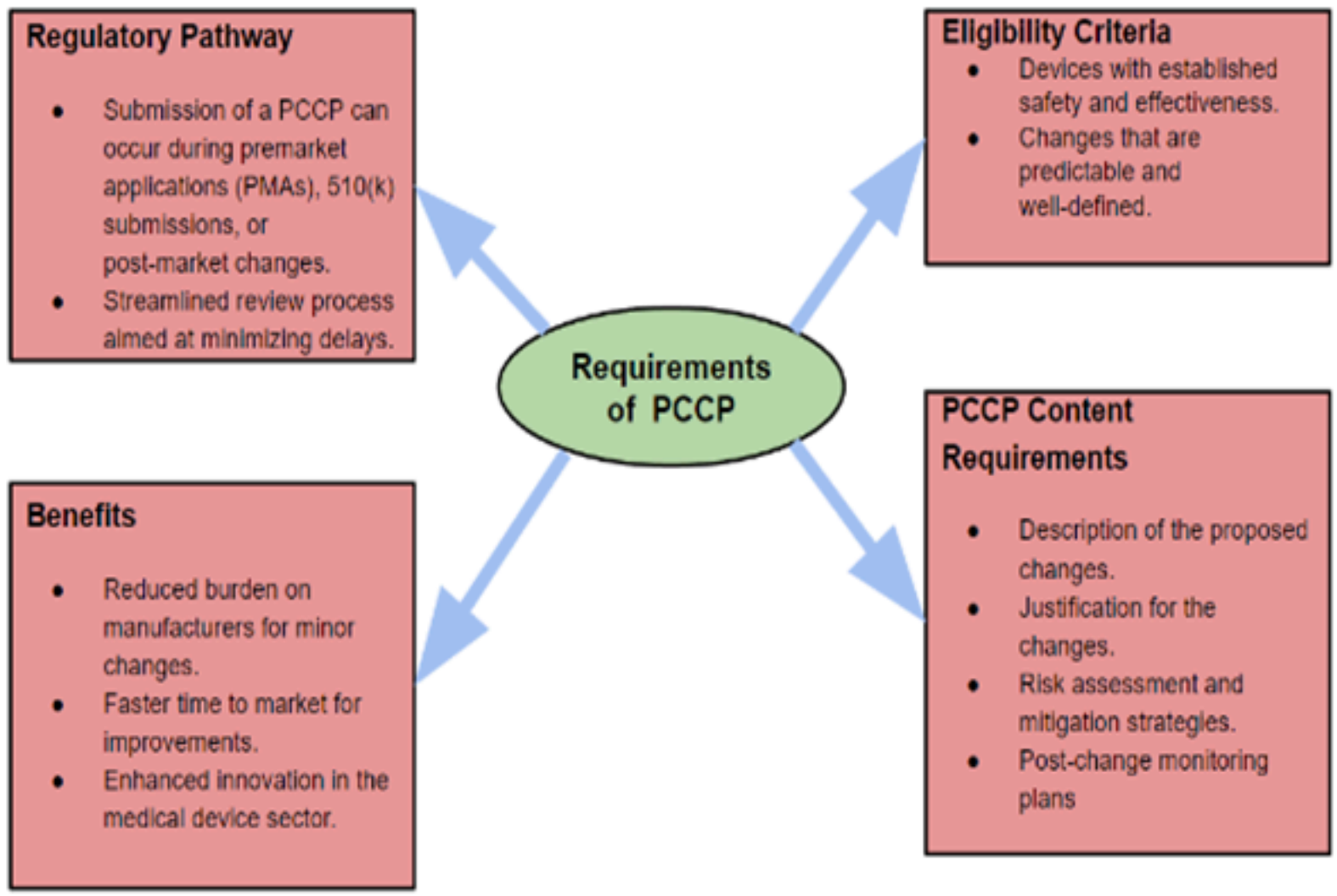
The FDA has introduced draft guidance on Predetermined Change Control Plans (PCCPs) for medical devices. This approach helps manufacturers get approval for certain device changes in advance. Allowing these pre-approved changes makes the process more efficient while ensuring patient safety.

WHAT IS A PCCP?

- **A Predetermined Change Control Plan allows medical device manufacturers to define and document expected changes to their products.**
- **These changes can include adjustments in algorithms, user interface design, data inputs, materials, or labelling.**
- **By submitting a PCCP, manufacturers can get approval for these changes in advance instead of waiting for the usual premarket submission process.**
- **This framework is intended to reduce the regulatory burden, particularly for AI/ML-based software as a medical device (SaMD) or devices that require frequent updates.**

reachus@easyqsolutions.com https://easyqsolutions.com/

KEY COMPONENTS OF PCCP



Flowchart 1: PCCP Requirements

A predetermined change control plan is essential for managing changes in medical devices. By following a structured approach, organisations can ensure safety, compliance, and quality in their products. This proactive strategy not only protects patients but also enhances the organisation's credibility and reliability in the medical device market.

reachus@easyqsolutions.com https://easyqsolutions.com/

CASE STUDY: DIAGNOSTIC IMAGING SOFTWARE UPDATE

Context:
A manufacturer develops software that helps radiologists spot abnormalities in medical images using machine learning. They want to update the algorithm to improve its accuracy.

Steps to Implement a PCCP:

1.Define The Change:
The manufacturer decides to refine the algorithm to increase its sensitivity and specificity based on new clinical data.

2.Conduct Risk Assessment:
Engineers and Clinicians assess the change, determining it to be low-risk and likely to enhance diagnostic accuracy without compromising safety.

3.Document The Change:
The manufacturer creates a PCCP that includes:

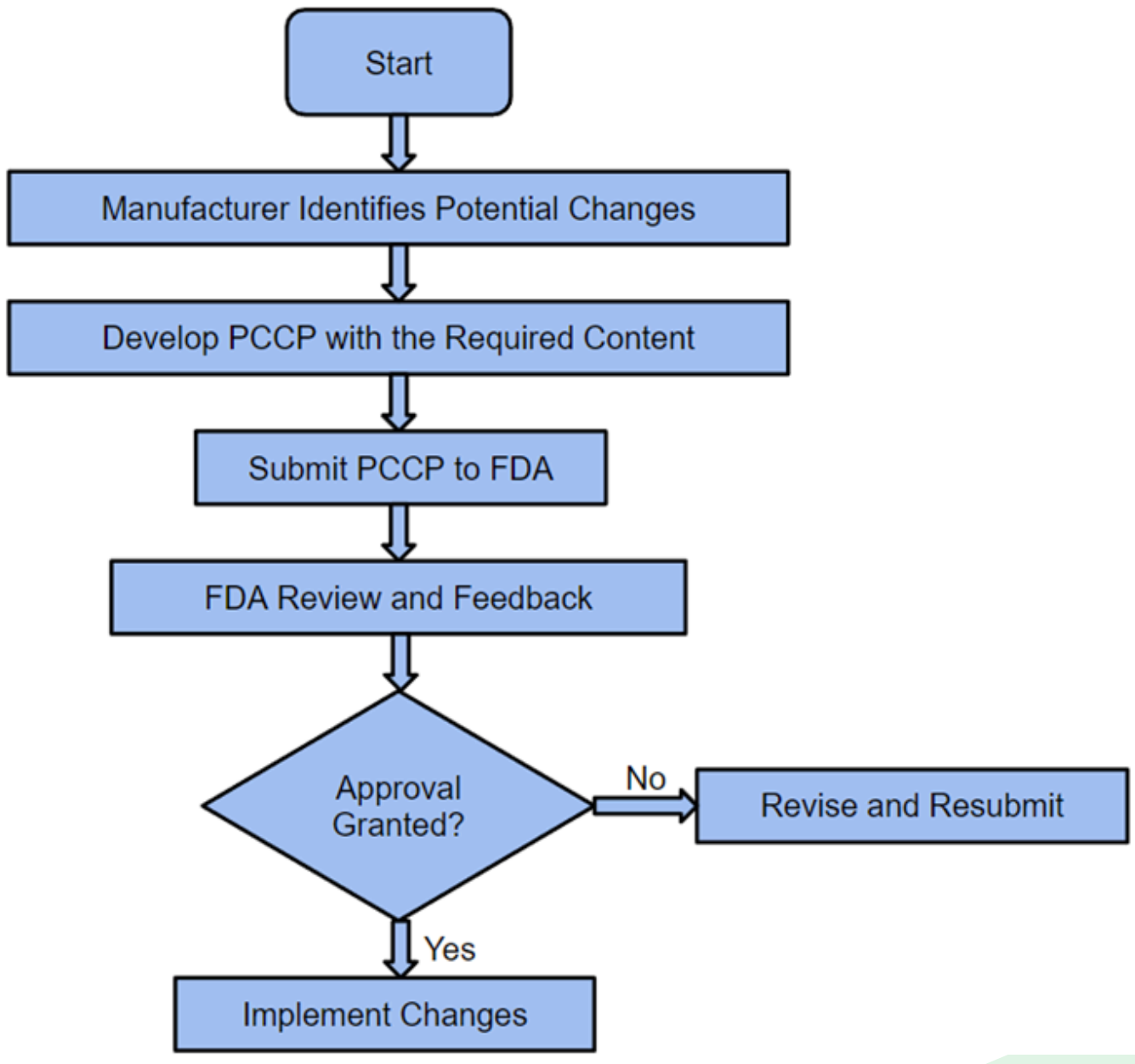
- **A description of the algorithm updates**
- **Reasons for the changes, backed by clinical data**
- **Risk assessment findings, showing safety will be maintained or improved**

4.Submit PCCP To FDA:
The manufacturer submits the PCCP to the FDA, demonstrating how the changes comply with regulations.

5.Implement The Change:
After FDA approval, the manufacturer rolls out the updated algorithm and trains healthcare professionals on the new features.

6.Post-Implementation Monitoring:
The manufacturer sets up a system to track the algorithm's performance in real-world settings, gathering data on its effectiveness and user feedback to ensure it remains safe and effective.

PROCESS OVERVIEW



reachus@easyqsolutionns.com
https:easyqsolutions.com