



**Global Harmonization Working Party**

Towards Medical Device Harmonization

# Introduction to Regulatory Excellence

Defining and Assessing Regulatory Excellence

# Core Elements of Regulatory Excellence\*

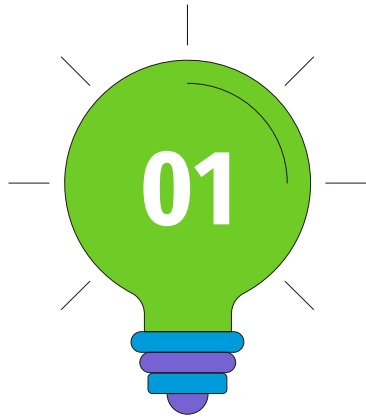


# Regulatory Excellence in Action – Good Regulatory Practice\*



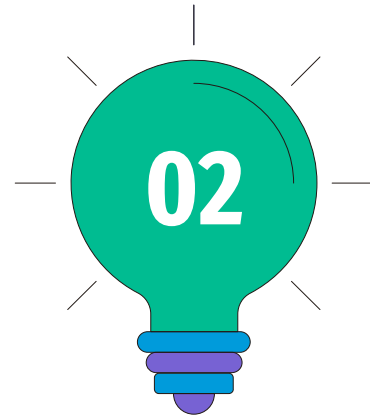
\*WHO Expert Committee on Specifications for Pharmaceutical Preparations, Annex 11 – Good regulatory practices in the regulation of medical products

# Assessing Regulatory Excellence – A few considerations



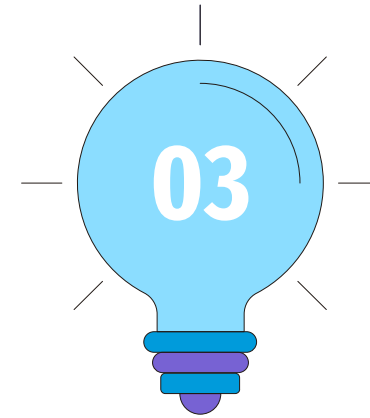
## **Timely Access**

Are patients receiving timely access to safe and effective devices?



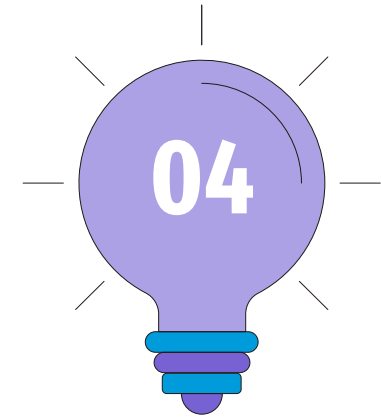
## **Efficient Use of Resources**

Are globally recognized guidances and standards adopted?



## **Least Burdensome**

Are requirements duplicative or unreasonably burdensome?



## **Build Competencies**

Are staff trained on new technologies and regulatory science methodologies?



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# Thank You