

# THE VALUE OF PHARMACEUTICAL EXCIPIENTS

a European perspective

## WHAT IS AN EXCIPIENT?

**”Any constituent of a medicinal product other than the active substance and the packaging material.”**

(Article 1(1)(a)3b DIRECTIVE 2011/62/EU on falsified medicinal products)

## WHAT ABOUT EXCIPIENTS?

**1200**



There are more than **1,200**  
**excipients** used in medicines



Those used depend on many factors  
including the **drug type**, **route of**  
**administration** and **dosage form**



Excipients are diverse materials from  
many origins, **animal**, **vegetable** or  
**mineral**



Many are not exclusive to medicines, but are used  
widely in **food** and **cosmetic industries**



Whatever their origin, however they are developed,  
made and handled, excipients **must not**  
**compromise quality** or **harm patients**

## WHAT CAN EXCIPIENTS DO?



Act as  
**filler/diluent**  
for highly potent  
medicines



Enhance  
**solubility** for  
poorly soluble  
medicines



**Control the rate**  
of drug release  
and bioavailability

# INNOVATION & DEVELOPMENT

Excipients can boost research and innovation into medicines and:



**Increase access** to new drugs (for poorly soluble, unstable drugs)



**Provide alternative routes** of delivery and dosage forms (easier to use, taste better)



**Improve patient compliance** (reduce frequency of dosing, extend duration of action)

It can take **10-15 years** for such a new drug formulation to move from the laboratory to the market

## HOW ARE THEY MANUFACTURED?



Excipients are mostly produced on a large scale using traditional chemical or biosynthetic processes

## REGULATIONS

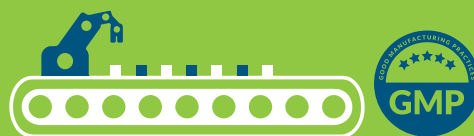
Excipient manufacturers in general are **not covered by EU law directly**. The manufacturer of the medicinal product must ensure excipients and their suppliers are controlled appropriately



The key EU excipients regulatory references are: **2011/62/EU Falsified Medicines Directive**, **European Commission Guidelines on Risk Assessment EC2015/C95/02** and **Eudralex Vol 4, Part 1, Chapter 5 Starting Materials**

## GMP & QUALITY STANDARDS

Medicines must be **safe, effective and of high quality**. So all ingredients including excipients should be made according to **Good Manufacturing Practices (GMP)**



Excipients manufacturers may apply standards from a **wide range of markets including food and cosmetics**. For medicines, the voluntary guidance in the **IPEC/PQG GMP Guide** is an important reference

## EXCIPIENTS MATTER!



They can represent the biggest part of the medicines (up to 95%)



The patient can consume more excipient than active ingredient



They have an important influence on drug safety



**IT IS ESSENTIAL THAT EXCIPIENT MANUFACTURERS, DISTRIBUTORS AND EXCIPIENT USERS COMPLY WITH ALL EXCIPIENTS STANDARDS AND REGULATIONS TO PROTECT PATIENTS**

**THAT'S THE VALUE EXCIPIENTS BRING TO MEDICINES AND PATIENTS!**