PRESERVE / PROTECT / NURTURE

PLANER Limited
110 Windmill Road
Sunbury-on-Thames
Middlesex
TW16 7HD
United Kingdom

Tel: +44 (0)1932 755000
www.planer.com
enquiries@planer.com

A Hamilton Thorne Group Company

GMP Statement Regarding Planer Products

Most Pharmaceutical companies are required to operate within Good Manufacturing Practice (GMP) regulations. Other related areas include distribution (GDP), Laboratory (GLP) and Clinical Practice (GCP). These are collectively referred to as GxP.

The scope of GMP Directive 2003/94/EC clearly states that it is aimed at Medicinal Products and Investigational Medicinal Products.

Article 1

Scope

This Directive lays down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use whose manufacture requires the authorisation referred to in Article 40 of Directive 2001/83/EC and in respect of investigational medicinal products for human use whose manufacture requires the authorisation referred to in Article 13 of Directive 2001/20/EC.

Article 2

Definitions

For the purposes of this Directive, the following definitions shall apply:

1. 'medicinal product' means any product as defined in Article 1(2) of Directive 2001/83/EC;

2. 'investigational medicinal product' means any product as defined in Article 2(d) of Directive 2001/20/EC;

The definition of a Medicinal Product from 2001/83/EC is:

PLANER Limited is registered in England. Company registration number: 00651504
Registered office: 110 Windmill Road, Sunbury-on-Thames, Middlesex, TW16 7HD, United Kingdom
Tel: +44 (0)1932 755000, www.planer.com, enquiries@planer.com
A Hamilton Thorne Group Company

2. *Medicinal product:*

(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or

(b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

3. *Substance:*

Any matter irrespective of origin which may be:

— human, e.g.

human blood and human blood products;

— animal, e.g.

micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products;

— vegetable, e.g.

micro-organisms, plants, parts of plants, vegetable secretions, extracts;

— chemical, e.g.

elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis.

The definition of an Investigational Medicinal Product from 2001/20/EC is:

(d) 'investigational medicinal product': a pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including products already with a marketing authorisation but used or assembled (formulated or packaged) in a way different from the authorised form, or when used for an unauthorised indication, or when used to gain further information about the authorised form;

What does this mean for Planer Equipment?

Planer Ltd is a Medical Device Manufacturer, not a pharmaceutical company.

Clearly the products manufactured by Planer are neither a Medicinal Product nor an Investigational Medicinal Product. They are not a substance either. The products manufactured at Planer fall outside of scope of the GMP Directive.

The GMP regulations do not therefore apply to Planer Ltd.

PLANER Limited is registered in England. Company registration number: 00651504
Registered office: 110 Windmill Road, Sunbury-on-Thames, Middlesex, TW16 7HD, United Kingdom
Tel: +44 (0)1932 755000, www.planer.com, enquiries@planer.com
A Hamilton Thorne Group Company