Project Summary

Code of Good Manufacturing Practice for Distillation of Tea Tree Oil

October 2020 - March 2021

Background

Currently all members of the Australian Tea Tree Industry Association (ATTIA) must abide by the industry code of practice for the production of tea tree oil. The code of practice provides fundamental quality objectives and requires basic record keeping. In addition those wishing to export their oils for medicinal use must be licensed by the Therapeutic Goods Administration and comply with PIC/s GMP (Part II). This requires substantial resources and expertise in quality assurance paradigms to establish and maintain.

A preliminary gap-analysis indicated that, in most cases the code of practice calls for records, whereas ‘Good Manufacturing Practice (GMP) paradigms’ merit risk management and control of critical processes; as well a number of proactive undertakings and documented procedures. This project aims to bridge the gap between the two standards; providing industry with a recognised standard that meets their needs and permits transition to PIC/s GMP, where desired.

Objectives

To establish an auditable code of Good Manufacturing Practice (GMP) and relevant implementation resources specifically designed for distillers of Australian tea tree oil. Once established, this code will become the standard for accreditation of demonstrably compliant manufacturers.

Research

The project will be divided into three phases:

1. Industry input will be sought following gap analysis, site investigations and drafting of the standard.

2. Once the standard, and systems for accreditation established in partnership with the industry association are finalised prepare GMP relevant resources such as “Standard Operating Procedures”.

3. Present the standard, the implementation resources and the pathways to accreditation and certification at a distillers’ forum, to be hosted by ATTIA.

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Expected outcomes and implications

The Code of GMP for Distillation of TTO will provide industry with an accreditation standard, expected to facilitate new supply, including export opportunities for demonstrably compliant distillers.

Global markets are increasingly demanding auditable accreditation and the Australian industry has identified an excellent opportunity to supply those long term, sustainable markets. Both the statutory regulators in international markets and the manufacturers purchasing Australian tea tree oil require quality assured safe and effective ingredients for cosmetic, therapeutic and industrial formulations.

The successful completion of the project will provide a quality assurance system that is internationally accepted that will allow for increased market access globally for Australian tea tree oil.

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