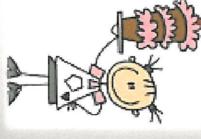


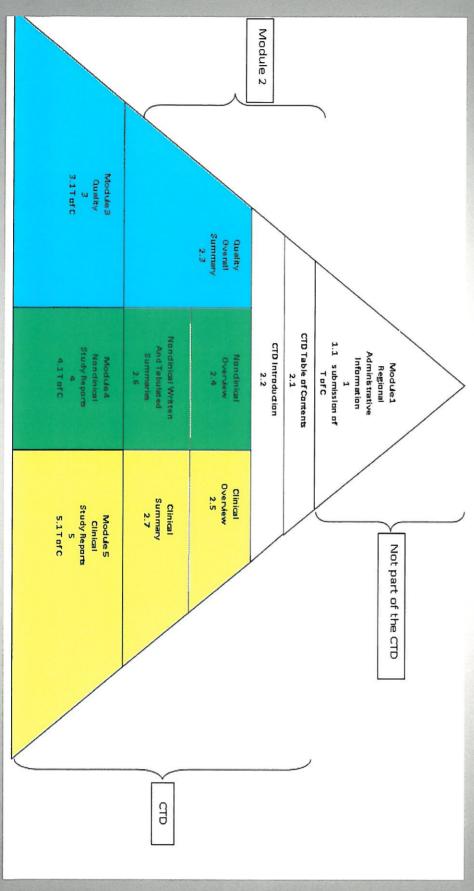
The ZA CTD It's a piece of cake



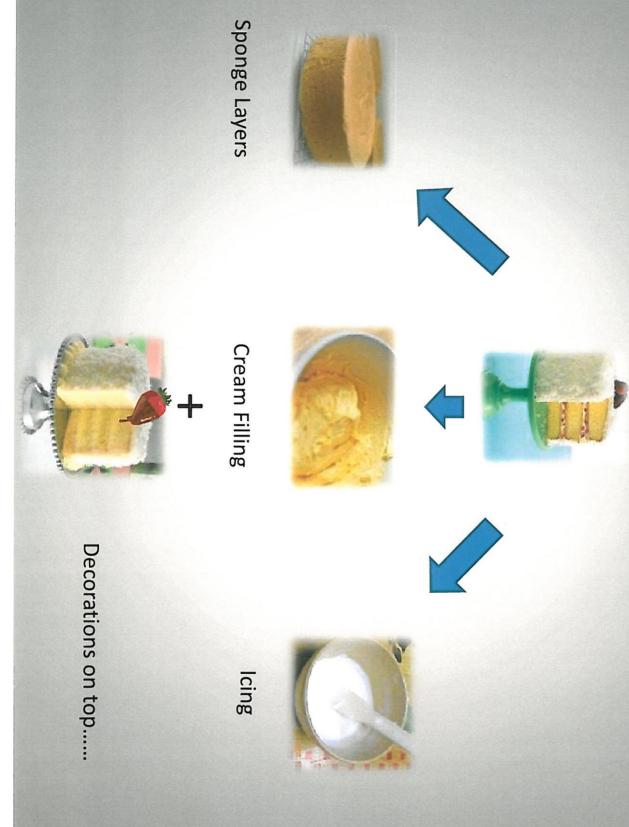
SAPRAA – 15 September 20. Hilde Rodseth

INTRODUCTION

The CTD is a dossier format:

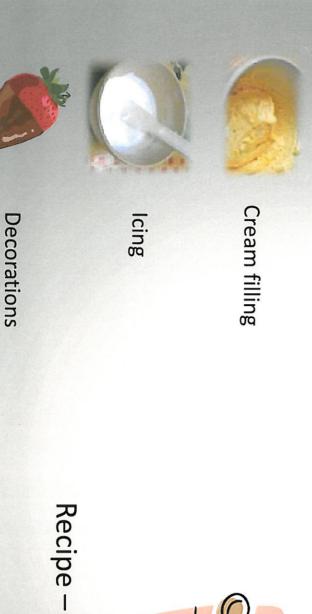


Dossier Format + Requirements = ZA CTD



Has to bake the cake from scratch Local ZA Company

Multi-national Company Gets basic cake from overseas Just need to add:





Recipe – in the MCC's ZA CTD
Guidelines

EU CTD into a ZA CTD cake. BIZA document created for decorating an

Purpose:

- Highlight areas where ZA application goes beyond EU CTD [= need for fillers]
- Guide an EU regulatory partner guidelines] regarding the recipes [= source in ZA

information required for a ZA CTD This document is **not** a comprehensive overview of all

ZA CTD vs EU CTD Modules 2, 3, 4 and 5



Layers

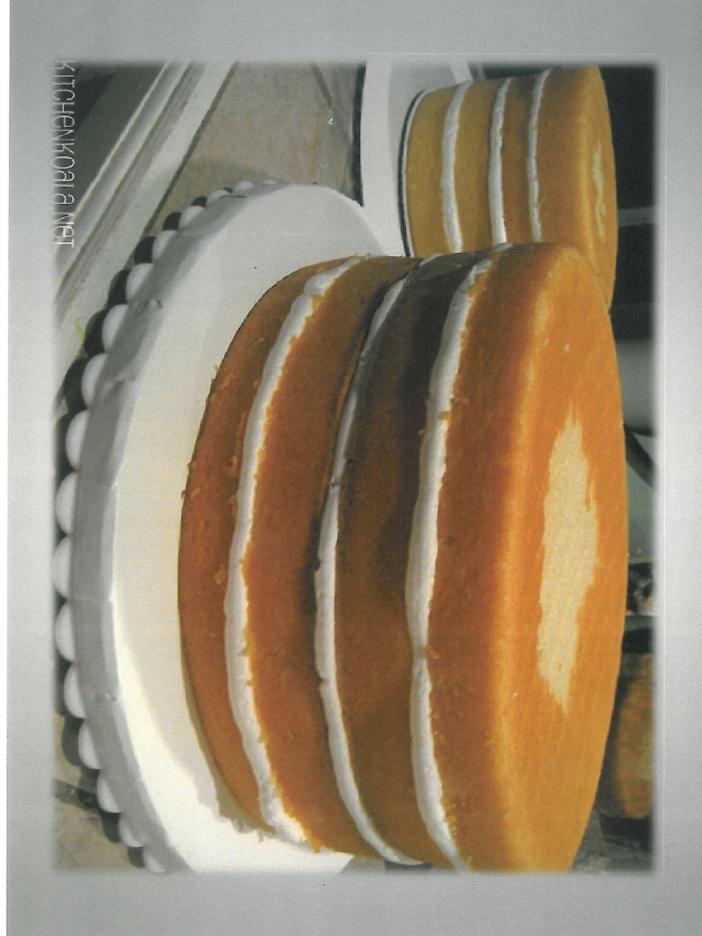


Microsoft Office Word Document

Cream Filling



lcing

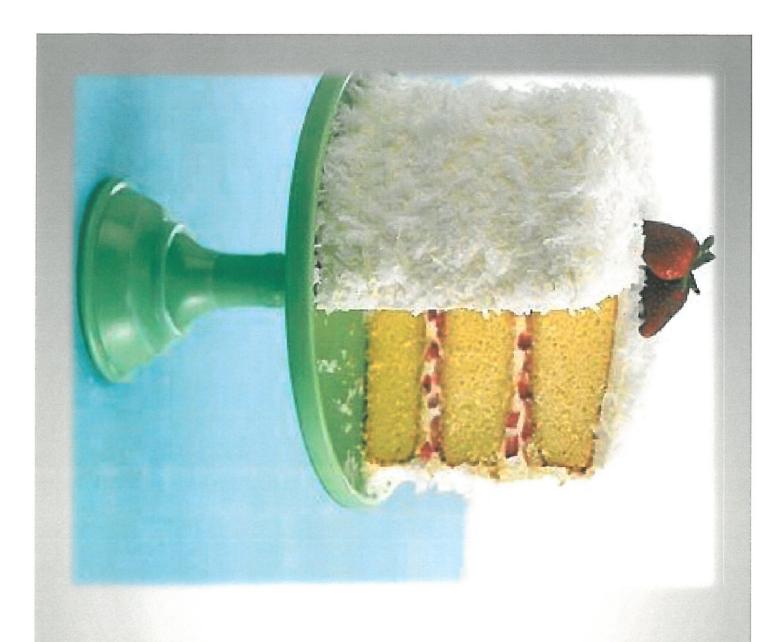


Module 2 Module3 Quality 3 Quality Overall Summary 2.3 CTD Table of Contents Nondinical Written And Tabulated Nondinical Study Reports 4 CTD Introduction 1.1 submission of TofC Module 1 Regional Administrative Information Nondinical Overview Summaries Module 4 4.1 TofC Overview 2.5 Clinical Summary 2.7 Module 5 Clinical Study Reports Clinical 5.1TofC Not part of the CTD Microsoft Office Word Document

d D

MODULE 1





The Final ZA CTD ZA CTD to to be Served

Conclusion

- The ZA CTD is a very rich cake
- to make a ZA CTD The EU CTD needs a lot of 'decorating'
- Question is this really necessary in all cases, or is there opportunity to reduce our regulatory indigestion?





उप्राथिक क्रिक्र क्रिक्ट प्रमुड