



Variations Workshop

10 & 12 August 2022

**Hosted online, by SAAP
Presented by Henriette Vienings**

Overview of Training

The online training will take place over 2 days, using MS Teams ® as the Platform for the training.

The training is structured as 2 half-day sessions from 11:00 – 14:30 with a 30 - minute lunch/comfort break.

The training will take the delegates through the various guidelines, templates and websites. It will address decision-making and process flow.

The topics that will be covered over the 2 days include:

1. Understanding the relationship between the EU variation legislation/guidelines and the South African (ZA) guidelines that address variations; including the evaluations processes, e.g. Business as Usual, Backlog, etc.
2. The types of variations and how to determine the type(s) of variation(s), including grouping of variations into a regulatory activity.
3. Determining the fees payable for a regulatory activity related to a variation.
4. The common regulatory documentation needed for a variation application, including the various forms and templates to use for variations.
5. The variation submission processes and portals.

Training Outcomes

Delegates should have an understanding of the following by the end of the training:

1. The references to use when working on a variation.
2. The individual documents required to successfully submit a variation application.
3. How to determine the type of variation and decide on the feasibility of combining various changes into one application or submitting multiple applications.
4. Writing the cover letter that fits the application – considering submission process and online platforms. Dossier maintenance – when to supersede dossier content

Presenter

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