



## Questions & Answers

### What is the Nanokinetik NeeS TOC Builder?

The Nanokinetik NeeS TOC Builder is a user-friendly application which automatically generates a Table of Contents for electronic submissions in the NeeS format and is fully compliant with the new NeeS validation criteria. The application requires no knowledge about PDF creation and can create a series of Tables of Contents (TOCs) in a couple of seconds. The Nanokinetik NeeS TOC Builder is a cost effective, efficient instrument and requires no special training compared to other tools for publishing electronic submissions in the NeeS and eCTD formats.

### Who is using NeeS TOC Builder?

The Nanokinetik NeeS TOC Builder is based on concepts which are being used globally by large originator and generic companies, their affiliates, and partners (CROs). This software is popular because of its simplicity and effectiveness in creating NeeS submissions. The TOC builder is being used on a daily basis to submit NeeS submissions in various procedures and regulatory activities to EU and non-EU national competent authorities.

### What are the latest improvements in the Nanokinetik NeeS TOC Builder?

The Nanokinetik TOC Builder creates electronic submissions in the NeeS format which are compatible with all NeeS specifications and validation criteria. The resulting NeeS submission enables applicants to submit electronic

submissions which can pass all validation criteria ('Pass/Fail' and 'Best Practice,' including 'inherit zoom,' and 'fast web viewable'). In addition, it provides improved navigation aids in TOCs by providing a back link and a customizable header.

### Do I need a document management system (DMS) to produce a NeeS submission?

No. Only standard office tools (a network drive where the content is stored, office and PDF tools, a TOC builder, and free NeeS validator) are needed.

### How do we get the TOC builder?

Please see Nanokinetik's order form at the following address: [www.nanokinetik.com](http://www.nanokinetik.com)

- **Creates hyperlinked Tables of Contents (TOC)**
- **Passes all Pass/Fail and Best Practice criteria**
- **All created hyperlinks are relative**
- **All hyperlinks have the 'inherit zoom' level set**
- **The PDFs for the TOC feature an active 'fast web view'**
- **Improved navigational aids in the Tables of Contents: back link**
- **A customisable header in all TOCs with the company name**

