



Ennov InSight Validator 5.1.19 Release Notes

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Chapter 1. Ennov InSight Validator 5.1.19 Release Notes

Ennov InSight Validator 5.1.19 Release Notes

This document describes a sub-minor release provided to support Ennov InSight Validator 5.1.19.

To make this sub-minor release available to customers, it has undergone the first product install and testing by our Quality Control specialists.

Ennov InSight Validator 5.1.19 Details

This sub-minor release is not a general release of Ennov InSight Validator.


This release package contains validation criteria support and must be applied to Ennov InSight Validator 5.1.19.


This enhancement is supplied as a ZIP file.


Component	Version	Customizable
InSight Validator-Setup.exe	5.1.19.6	No

New in Ennov InSight Validator 5.1.19

The following enhancements are included in this release.

Enhancement	Description
Regulatory Update	<p>TW Region: Ennov InSight Validator supports the updated Taiwan v1.2 (also known as eCTD-R2) validation rules for eCTD.</p> <ul style="list-style-type: none">Revised criteria: C.3, D.3, E.3, F.3, O.3, O.BP1, O.BP2 <p> Note: The start date for Taiwan v1.2 as announced by Taiwan Food and Drug Administration has now been changed. For more details, see the TFDA website.</p>
Regulatory Update	<p>US Region: Ennov InSight Validator supports the valid-values.xml v6.0 for FDA.</p>

Enhancement	Description
	<ul style="list-style-type: none"> Revised criteria: 2002, 1255 <p> Note: FDA submissions may fail validation if your corporate policies prevent use of http protocols. The FDA's us-regional.xml backbone specifies that http can be used to download the dtd. If your corporate policies prevent the use of non-secure http protocols, users will receive an error stating that the XML did not pass validation with the schema (DTD) and attribute files [Agency No. = 2002]. This error can be fixed by manually editing the us-regional.xml file to change the protocol to https. Editing the us-regional.xml file will allow the submission to pass validation.</p>
Regulatory Update	<p>AU Region: Ennov InSight Validator supports the updated TGA version 3.2 validation rules for eCTD.</p> <ul style="list-style-type: none"> Revised criteria: 2.8, 2.9, 3.7, 4.1.23, 4.2.11, 5.3 New criteria: 2.10, 2.11 <p>You can access the AU v3.2 validation warning.xml best practice document here.</p>
Regulatory Update	<p>ZA Region: Ennov InSight Validator now supports the new updated defined list.</p> <p>For details, see Defined Lists and Matrices Updates (on page 7).</p> <ul style="list-style-type: none"> Revised criteria: 4.8.1 to 4.8.4, 4.7.1b, 4.7.11b, 4.7.11d, 4.7.12b, 4.7.13b, 4.7.15b, 4.7.21b
Regulatory Update	<p>EU Region: Ennov InSight Validator supports the updated EMA version 8.2 validation rules for eCTD.</p>

Enhancement	Description
	<ul style="list-style-type: none"> • Revised criteria:15.11, 15.12 • New criteria:16.6 and 16.7 <p> Note: Validation criteria v8.2 will be accepted starting 1 October 2025. For details, see EMA web site.</p>

Defined Lists and Matrices Updates

The table below details the Defined Lists and Matrices updates for SAHPRA.

Defined List & Matrix	Version	Update
Application Type	2.0	Updated description for app-type-2, 3, 4, 5, 6, 7 Addition app-type-8, 9
Document Matrix	3.0	Update to align with additional Submission Types for the major config update of March 2025
Evaluation Pathway	1.1	Renamed value for eval-path-5
Sequence Type	3.0	Additional sequence types-13, 14, 15, 16, 17, 18, 19, 20, 21 and renamed sequence types-3, 4, 5, 6, 10, 11, 12
Submission Type Matrix	2.1	Pairing of submission types-related
Submission-lead	2.0	Added sub-lead 7, corrected spelling for sub-lead-2
Submission-Type	3.0	Additional subtypes added-45, 47, 48, 49, 50, renaming of subtypes subtypes-14, 22, 23, 32, 38, 39, 40, 44

Chapter 2. Ennov InSight Validator 5.1.18 Release Notes

Ennov InSight Validator 5.1.18 Release Notes

This document describes a sub-minor release provided to support Ennov InSight Validator 5.1.18.

To make this sub-minor release available to customers, it has undergone the first product install and testing by our Quality Control specialists.

Ennov InSight Validator 5.1.18 Details

This sub-minor release is not a general release of Ennov InSight Validator.

This release package contains validation criteria support and must be applied to Ennov InSight Validator 5.1.18.

This enhancement is supplied as a ZIP file.

Component	Version	Customizable
InSight Validator-Setup.exe	5.1.18.10	No

New in Ennov InSight Validator 5.1.18

The following enhancements, functional changes, and updates are included with this release.

Enhancement	Description
Regulatory update	Ennov InSight Validator now supports Ukraine (UA) eCTD v1.0 submissions.
Regulatory update	CA Region: Ennov InSight Validator supports the updated Health Canada version 5.3 validation rules for eCTD. <ul style="list-style-type: none">• Revised criteria: F09, G22, H08, I05, I09• New criteria: H21
Regulatory update	CA Region: Ennov InSight Validator supports the updated Health Canada version 5.3 validation rules for non-eCTD. <ul style="list-style-type: none">• Revised criteria: A08, I08, I09
Regulatory update	ZA Region: Ennov InSight Validator now supports the new updated document-matrix.xml file v2.3. <ul style="list-style-type: none">• Revised criteria: 4.8.1 to 4.8.4

Resolved Issues: Ennov InSight Validator 5.1.18

The following issues that were reported to Technical Support have been resolved. Issues are listed in descending order by their tracking numbers. Customer incident numbers that were recorded when the issues were reported are included in brackets [#####] following the tracking number.

If an issue was resolved in a hotfix before this release, the hotfix build number is included in the table.

Defect	Hotfix Build	Description
DE32348		When validating submissions for AU, CN, and ZA regions, Ennov InSight Validator failed to identify broken hyperlinks. This issue is resolved. Now, Ennov InSight Validator correctly identifies the broken hyperlinks and fails the corresponding criterion.
DE32211		The criterion I11 failed even if latest acceptable version of the document was used for Master file, Drug, or Device type. This issue is resolved. Now, the criterion I11 passes if latest acceptable version of the document is used for Master file, Drug, or Device type.

Chapter 3. Ennov InSight Validator 5.1.17 Release Notes

Ennov InSight Validator 5.1.17 Release Notes

This document describes a sub-minor release provided to support Ennov InSight Validator 5.1.17 for the European Union specification updates.

To make this sub-minor release available to customers, it has undergone the first product install and testing by our Quality Control specialists.

New in Ennov InSight Validator 5.1.17

The following enhancements, functional changes, and updates are included with this release.

Regulatory Updates

Support for EU M1 v3.1 and validation criteria v8.1.

Support for ZA validation criteria v3.1.1.

Ennov InSight Validator 5.1.17 Details

This sub-minor release is not a general release of Ennov InSight Validator.

This release package contains validation criteria support and must be applied to Ennov InSight Validator 5.1.17. This enhancement is supplied as a ZIP file.

Component	Version	Cus-tomizable
InSight Validator-Set-up.exe	5.1.17.5	No

Resolved Issues: Ennov InSight Validator 5.1.17

The following issues that were reported to Technical Support have been resolved. Issues are listed in descending order by their tracking numbers. Customer incident numbers that were recorded when the issues were reported are included in brackets [#####] following the tracking number.

If an issue was resolved in a hotfix before this release, the hotfix build number is included in the table.

Defect	Hot-fix Build	Description
DE32116[TASK1421168, INC0357403]		Region ZA 3.1 eCTD: Ennov InSight Validator failed to validate the code-version and sub-type for the submission criterion 4.7.11b and the sequence criterion 4.7.15b.

Defect	Hot-fix Build	Description
		This issue is resolved. Now, Ennov InSight Validator correctly validates code-version and sub-type for the submission criterion 4.7.11b and the sequence criterion 4.7.15b.
DE32082[TASK1386935, INC0355956]		Region ZA 3.1 eCTD: Ennov InSight Validator incorrectly failed a submission for the criterion 4.7.21a. This issue has been resolved. Now, Ennov InSight Validator correctly passes a submission for the criterion 4.7.21a.

Chapter 4. Ennov InSight Validator 5.1.16 Release Notes

Ennov InSight Validator 5.1.16 Release Notes

This document describes a sub-minor release provided to support Ennov InSight Validator 5.1.16 for the South Africa specification updates.

To make this sub-minor release available to customers, it has undergone the first product install and testing by our Quality Control specialists.

New in Ennov InSight Validator 5.1.16

The following enhancements, functional changes, and updates are included with this release.

Regulatory Updates

- Support for ZA-SAHpra eCTD specification, validation criteria v3.1.

Regional Settings Updates

The **Regional DTD** option is updated to include **za-regional.xsd** and **za-regional.xsl** files for ZA version 3.1.

User Preferences Updates

The **Errors Only Report Preferences** option is updated to include the new severity types for ZA eCTD: **Error, Warning, Information**. See *Criteria Severity and Corresponding Validation Status* in the User Guide.

Ennov InSight Validator 5.1.16 Details

This sub-minor release is not a general release of Ennov InSight Validator 5.1.

This release package contains validation criteria support and must be applied to Ennov InSight Validator 5.1.16. This enhancement is supplied as a ZIP file.

Component	Version	Cus- tomizable
InSight Validator-Set-up.exe	5.1.16.13	No

Enhancements: Ennov InSight Validator 5.1.16

Requested new features and enhancements are included in each release. The items are listed in descending order by their tracking numbers. Customer case numbers that were recorded when the enhancements were requested are included in brackets [#####] following the tracking number.

The Ennov InSight Validator 5.1.16 includes the following enhancements:

Enhancement	Description
Regulatory update	ZA Region: Ennov InSight Validator supports the new SAHPRA eCTD specification v3.1.

Chapter 5. Ennov InSight Validator 5.1.15 Release Notes

Ennov InSight Validator 5.1.15 Release Notes

This document describes a sub-minor release provided to support Ennov InSight Validator 5.1.15 for the Health Canada specification updates.

To make this sub-minor release available to customers, it has undergone the first product install and testing by our Quality Control specialists.

New in Ennov InSight Validator 5.1.15

The following enhancements, functional changes, and updates are included with this release.

Regulatory Updates

- Health Canada updated eCTD validation rules v.5.2.
- Health Canada updated non-eCTD format, validation rules v.5.2.

Ennov InSight Validator 5.1.15 Details

This sub-minor release is not a general release of Ennov InSight Validator 5.1.

This release package contains Health Canada eCTD and non-eCTD validation criteria v5.2 support and must be applied to Ennov InSight Validator 5.1.15. This enhancement is supplied as a ZIP file.

Component	Version	Cus- tomizable
InSight Validator-Set-up.exe	5.1.15.0002	No

Enhancements: Ennov InSight Validator 5.1.15

Requested new features and enhancements are included in each release. The items are listed in descending order by their tracking numbers. Customer case numbers that were recorded when the enhancements were requested are included in brackets [#####] following the tracking number.

The Ennov InSight Validator 5.1.15 includes the following enhancements:

Enhancement	Description
Regulatory update	CA Region: Ennov InSight Validator supports the updated Health Canada Version 5.2 validation rules for eCTD.

Enhancement	Description
	<ul style="list-style-type: none"> • Revised criteria: B32, B44, B47, B48, I02, I03, I04, I05, I06, I07, I08, I09. • New criteria: B49, I11.
Regulatory update	<p>CA Region: Ennov InSight Validator supports the updated Health Canada version 5.2 validation rules for non-eCTD.</p> <ul style="list-style-type: none"> • Revised criteria: A03a, A03b, A08, I06, I08, I09, I10. • New criteria: B49, I11.

Chapter 6. Ennov InSight Validator 5.1.14 Release Notes

Ennov InSight Validator 5.1.14 Release Notes

This document describes a sub-minor release provided to support Ennov InSight Validator version 5.1.14 high priority defect fixes and hot fixes ports.

To make this sub-minor release available to customers, it has undergone the first product install and testing by our Quality Control specialists.

Ennov InSight Validator 5.1.14 Details

This sub-minor release is not a general release of Ennov InSight Validator 5.1.

This release package must be applied to Ennov InSight Validator 5.1.14. This enhancement is supplied as a ZIP file.

Component	Version	Cus- tomizable
InSight Validator-Set-up.exe	5.1.14.2	No

Resolved Issues: Ennov InSight Validator 5.1.14

The following issues that were reported to Technical Support have been resolved. Issues are listed in descending order by their tracking numbers. Customer incident numbers that were recorded when the issues were reported are included in brackets [#####] following the tracking number.

If an issue was resolved in a hotfix before this release, the hotfix build number is included in the table.

Name	Hot- fix Build	Description
DE30108;[TASK0049485, INC0226261]	N/A	For eCTD submissions that used ICH - eCTD 3.2 DTD, Ennov InSight Validator incorrectly showed Fail status with <code>lang</code> tag for the 11.10 criterion. This issue is resolved. Now, Ennov InSight Validator successfully processes this criterion.
DE29876;[TASK0048602]	N/A	If the new version of FDA 1571 form was used in a submission, Ennov InSight Validator incorrectly failed the submission under 5029 and 5030 criteria . This issue is resolved. Now, Ennov InSight Validator successfully processes these criteria.
DE29775;[TASK0048253, INC0047668, PRB0044567, CS0620030,CS0674753]	N/A	Ennov InSight Validator incorrectly failed submissions for criterion 1734 if they included Trial Sets (ts.xpt) data sets. This issue is resolved. Now, all the previous sequences will be checked for the presence of ts.xpt file.

Chapter 7. Ennov InSight Validator 5.1.13 Release Notes

Ennov InSight Validator 5.1.13 Release Notes

This document describes a sub-minor release provided to support Ennov InSight Validator version 5.1.13 for the US FDA specification updates and high priority defect fixes and hot fixes ports.

To make this sub-minor release available to customers, it has undergone the first product install and testing by our Quality Control specialists.

New in Ennov InSight Validator 5.1.13

The following enhancements, functional changes, and updates are included with this release.

US FDA Support Ennov InSight Validator 5.1.13 supports the FDA version 8.0 file format specifications:

- The Chemical files (.sdf file format) are now allowed only in M3 folder for v4.4.
- The Chemical files (.sdf file format) are now allowed only in M3.2.P.5.5 and M3.2.S.3.2 folders for v4.1, v4.2 and v4.3.

Ennov InSight Validator 5.1.13 Details

This sub-minor release is not a general release of Ennov InSight Validator 5.1.

This release package must be applied to Ennov InSight Validator 5.1.13. This enhancement is supplied as a ZIP file.

Component	Version	Cus- tomizable
InSight Validator-Set-up.exe	5.1.13.1	No

Resolved Issues: Ennov InSight Validator 5.1.13

The following issues that were reported to Technical Support have been resolved. Issues are listed in descending order by their tracking numbers. Customer incident numbers that were recorded when the issues were reported are included in brackets [#####] following the tracking number.

If an issue was resolved in a hotfix before this release, the hotfix build number is included in the table.

Name	Hotfix Build	Description
DE28546; [TASK0044430, INC0122153]	5.1.12.3	Ennov InSight Validator failed the 1737 and 1738 criteria for US FDA submissions when using the Use legacy error reporting and Enable TBD criteria options. This issue is resolved. Now, Ennov InSight Validator successfully processes these criteria.

Name	Hotfix Build	Description
DE29402	N/A	<p>Incorrect email address was included:</p> <ul style="list-style-type: none"> • in the email generated after a customer completed the product registration form. • on the alert messages for the following types of licenses: Reviewer, Reviewer Edit, Validation. <p>This issue is resolved. Now, the email is removed and the alert messages advise a user to contact ServiceNow for a license. The Help and Register buttons are removed for This product requires Registration! window.</p>
DE28335; [INC0108958]	5.1.12.3	Ennov InSight Validator failed the 11.10 criterion for EU submissions. This issue is resolved. Now, Ennov InSight Validator successfully processes this criterion.
DE28229; [INC0107299]	5.1.12.3	Ennov InSight Validator incorrectly reported error of 1736 criterion for module 4 of US FDA submissions. This issue is resolved. Now, Ennov InSight Validator processes 1736 criterion correctly.
DE26075; [INC0063249]	N/A	When the regional.xml file contained a leaf with Delete, Replace or, New operation and did not have a xlink:href attribute, the I04 criterion had an Error status. This issue is resolved. Now, Ennov InSight Validator successfully passes this criterion.

Chapter 8. Ennov InSight Validator 5.1.12 Release Notes

Ennov InSight Validator 5.1.12 Release Notes

This document describes a sub-minor release provided to support Ennov InSight Validator 5.1.12 for the US FDA and the Health Canada specification updates.

To make this sub-minor release available to customers, it has undergone the first product install and testing by our Quality Control specialists.

New in Ennov InSight Validator 5.1.12

The following enhancements, functional changes, and updates are included with this release.

Regulatory Updates

- US FDA eCTD M1 specification v2.5, submission standards version 4.4, validation criteria version 4.3 and 4.4.
- Health Canada updated eCTD validation rules v.5.1.
- Health Canada updated "non-eCTD electronic-only" format, validation rules v.5.1.

Regional Settings Updates

- New file extensions are added to *CA Regional Settings*. See *Preferences CA* in *Ennov InSight Validator 5.1 User Guide*.

About Page

The logo is replaced with on the *About* page. The copyright information is changed to © Calyx™ 2021.

Ennov InSight Validator 5.1.12 Details

This sub-minor release is not a general release of Ennov InSight Validator 5.1.

This release package contains US FDA version 4.4, validation criteria 4.3 and 4.4 support, and Health Canada eCTD/ NeeS validation criteria v5.1 support and must be applied to Ennov InSight Validator 5.1.12. This enhancement is supplied as a ZIP file.

Component	Version	Cus- tomizable
InSight Validator-Set-up.exe	5.1.12.2	No

Enhancements: Ennov InSight Validator 5.1.12

Requested new features and enhancements are included in each release. The items are listed in descending order by their tracking numbers. Customer case numbers that were recorded when the enhancements were requested are included in brackets [#####] following the tracking number.

The Ennov InSight Validator 5.1.12 includes the following enhancements:

- US Region: Ennov InSight Validator supports the new US FDA v4.4 eCTD, validation criteria 4.3 and 4.4.
- CA Region: Ennov InSight Validator supports the updated Health Canada Version 5.1 of the eCTD validation rules. Revised criteria: F14, F15, G22, G34.
- CA Region: Ennov InSight Validator supports the updated Health Canada version 5.1 of the "non-eCTD electronic-only" format validation rules. Revised criteria: A08, I08.

Resolved Issues: Ennov InSight Validator 5.1.12

The following issues that were reported to Technical Support have been resolved. Issues are listed in descending order by their tracking numbers. Customer incident numbers that were recorded when the issues were reported are included in brackets [#####] following the tracking number.

If an issue was resolved in a hotfix before this release, the hotfix build number is included in the table.

Name	Hot-fix Build	Description
DE26069; [INC0047668, PRB0044567, CS0620030 CS0674753]	N/A	When validating Module 5 documents of the US submissions, Data set validation error appeared for the 1734 criterion. This issue is resolved with the implementation of US FDA eCTD Module 1 specification version 4.4. Now, no errors appear for 1734 criterion.

Chapter 9. Ennov InSight Validator 5.1.11 Release Notes

Ennov InSight Validator 5.1.11 Release Notes

This document describes a sub-minor release provided to support Ennov InSight Validator 5.1.11 for the China specification updates.

To make this sub-minor release available to customers, it has undergone the first product install and testing by our Quality Control specialists.

New in Ennov InSight Validator 5.1.11

The following enhancements, functional changes, and updates are included with this release.

Regulatory Updates

- Support for China (CN) eCTD Module 1 version 1.0 (29-SEP-2021).
- Support for eCTD Data Standards version 4.3, validation criteria version 4.2.

Microsoft Windows 8.1 Not Supported

Ennov InSight Validator 5.1.11 no longer supports Microsoft Windows 8.1.

Ennov InSight Validator 5.1.11 Details

This sub-minor release is not a general release of Ennov InSight Validator 5.1.

This release package contains China eCTD Module 1 Version 1.0 support and must be applied to Ennov InSight Validator 5.1.11.

This enhancement is supplied as a ZIP file.

Component	Version	Cus- tomizable
InSight Validator-Set-up.exe	5.1.11.2	No

Resolved Issues: Ennov InSight Validator 5.1.11

The following issues that were reported to Technical Support have been resolved. Issues are listed in descending order by their tracking numbers. Customer incident numbers that were recorded when the issues were reported are included in brackets [#####] following the tracking number.

If an issue was resolved in a hotfix before this release, the hotfix build number is included in the table.

Name	Hot-fix Build	Description
863	N/A	Earlier versions of Ennov InSight Validator 5.1 did not use the latest specifications for the file format types. This issue is resolved with the support of for eCTD Data Standards version 4.3.
862; [INC0072875]	N/A	After performing the Technical Rejection Criteria (TRC) validation check on FDA submissions, errors were noticed in submission types where the ts.xpt files were absent for Module 4 and Module 5 documents. This issue is resolved. Now, the submissions pass the TRC validation.
857; [INC0055329]	N/A	Some errors related to the China DTD appeared in earlier versions of Ennov InSight Validator 5.1. Support for China (CN) eCTD Module 1 version 1.0 (29-SEP-2021) has been implemented starting with Ennov InSight Validator 5.1.11 and these errors no longer appear.

Chapter 10. Ennov InSight Validator 5.1 CHF 10 Release Notes

New in Ennov InSight Validator 5.1 CHF 10

Ennov InSight Validator 5.1 CHF 10 includes the following enhancements and functional changes.

Regulatory Updates

- Support for Taiwan FDA eCTD v1.0.
- Support for US FDA eCTD M1 specification v2.5, submission standards v4.1, validation criteria v4.1.

Media Backup of Submissions

The Media option to save the submission contents onto storage devices such as the CD or the DVD is no longer available.

Preferences Settings Updates

Arial Unicode MS font type is no longer supported by Microsoft and is not installed as a part of system. To continue to display the Unicode characters correctly, Ennov InSight Validator enables you to select a preferred font in User Preferences > Errors Only Report Preferences. See: *Select Font for Reports, Add Fonts for Reports, Delete Fonts for Reports*.

Details: Ennov InSight Validator 5.1 CHF 10

The Ennov InSight Validator 5.1 Release Notes contain information about updated files, new functionality, and any open issues and workarounds in Ennov InSight Validator 5.1.

This certified hotfix is an interim fix to issues that have been reported. It is not a general release of Ennov InSight Validator

This certified hotfix is supplied as a .zip file containing the following component(s) in a cumulative package set:

Component	Version	Cus- tomize
InSight Validator-Set-up.exe	5.1.0.124	No

Resolved Issues: Ennov InSight Validator 5.1 CHF 10

The following issues that were reported to Technical Support have been resolved. Issues are listed in descending order by their tracking numbers. Customer incident numbers that were recorded when the issues were reported are included in brackets [#####] following the tracking number.

If an issue was resolved in a hotfix before this CHF release, the hotfix build number is included in the table.

Name	Hot-fix Build	Description
856; [INC0049773]	N/A	CA region: Using the text "Initial" in a sequence description failed a submission under the F09 criterion. This issue is resolved. The list of descriptions is updated to the Health Canada eCTD format Validation Rules version 5.0.
855	N/A	As Arial Unicode MS font type is not supported and not installed as a part of system, Unicode characters were not recognized in PDF viewer for Errors Only Report and Full Report in Ennov InSight Validator. This issue was noticed for all the submissions with Unicode character, except for that of CN, JP, TW regions. This issue is resolved. You can now select a preferred font in the <i>Preferences</i> settings. See: <i>Select Font for Reports, Add Fonts for Reports, Delete Fonts for Reports</i> .

Chapter 11. Ennov InSight Validator 5.1 CHF 9 Release Notes

New in Ennov InSight Validator 5.1 CHF 9

Ennov InSight Validator 5.1 CHF 9 includes the following enhancements.

Regulatory Updates

- Health Canada updated eCTD validation rules v.5.0
- Health Canada updated "non-eCTD electronic-only" format, validation rules v5.0

Details: Ennov InSight Validator 5.1 CHF 9

The Ennov InSight Validator 5.1 Release Notes contain information about updated files, new functionality, and any open issues and workarounds in Ennov InSight Validator 5.1.

This certified hotfix is an interim fix to issues that have been reported. It is not a general release of Ennov InSight Validator

This certified hotfix is supplied as a **.zip** file containing the following component(s) in a cumulative package set:

Component	Version	Cus-tomize
InSight Validator-Setup.exe	5.1.0.117	No

Enhancements: Ennov InSight Validator 5.1 CHF 9

Requested new features and enhancements are included in each release. The items are listed in descending order by their tracking numbers. Customer case numbers that were recorded when the enhancements were requested are included in brackets [#####] following the tracking number.

The Ennov InSight Validator 5.1 CHF includes the following enhancements:

Issue	Description
Regulatory update	CA Region: Ennov InSight Validator supports the updated Health Canada Version 5.0 of the eCTD validation rules. <ul style="list-style-type: none">• Revised criteria: A09, B01, B32, B47, D03, F14, F15, F22, F25, F26, G22, G34, I04, I05, I06• New criteria: A10, B48, F28, I07, I08, I09
Regulatory update	CA Region: Ennov InSight Validator supports the updated Health Canada version 5.0 of the "non-eCTD electronic-only" format validation rules.

Issue	Description
	<ul style="list-style-type: none"> • Revised criteria: A09, B01, B32, B47, C05 • New criteria: B48, I06, I08, I09, I10 <p>Note: To conform to the A10 criterion, ensure the content of the current transaction is not the same as the other transactions within the dossier.</p>

Resolved Issues: Ennov InSight Validator 5.1 CHF 9

The following issues that were reported to Technical Support have been resolved. Issues are listed in descending order by their tracking numbers. Customer incident numbers that were recorded when the issues were reported are included in brackets [#####] following the tracking number.

If an issue was resolved in a hotfix before this CHF release, the hotfix build number is included in the table.

Name	Hotfix Build	Description
852; [INC0047287]	N/A	US region: Ennov InSight Validator incorrectly showed <code>Fail</code> status in the report for the 5040 criterion. This issue is resolved.
851; [INC0045022]	5.1.0.111	In Ennov InSight Validator 5.1 CHF 8, when validating a US submission, an error message about "fdast11" invalid value in submission type attribute appeared. This issue is resolved.

Chapter 12. Ennov InSight Validator 5.1 CHF 8 Release Notes

New in Ennov InSight Validator 5.1 CHF 8

Ennov InSight Validator 5.1 CHF 8 includes enhancements and also addresses prioritized hotfixes and known issues from previous versions.

Regulatory Updates

- US FDA eCTD Module 1 specification v2.4, validation criteria v3.8
- China NMPA eCTD specification v1.0, validation criteria v1.0 (draft, dated 17 September 2019)
- CH eCTD Module 1 specification v1.5, validation criteria v1.5
- JO eCTD Module 1 specification v1.1, validation criteria v1.1
- ZA eCTD Module 1 specification v3.0, validation criteria v.2.1
- CA "non-eCTD electronic-only" format, validation rules v4.4. Folders that do not match the required 4-digit format are recognized by Ennov InSight Validator as "non-eCTD electronic-only" submissions.

Regional Settings Updates

- The **NeeS Settings** option is added to GCC Regional Settings. See *Preferences GCC* in the User Guide.
- The **Nees Settings** option is added to CA Regional Settings. See *Preferences CA* in the User Guide.

Preferences Settings Updates

- The default **NeeS** settings tab is removed. Now, the NeeS settings are available along with the region settings in their respective tabs. **Note:** The **NeeS** settings are currently available for AU, CA, EU, and GCC regions only.
- The **PDF Version** text box validation criteria is updated. If the text box is empty, the PDF document of any version will be valid.

Validation Framework Updates

- The validation framework for GCC NeeS submissions is redesigned to provide agency-driven filtering of criteria and optimized PDF file processing that improves the overall performance of GCC NeeS submission validation. This helps to expedite future updates for new validation criteria releases from the GCC NeeS Validation Criteria version 1.2.
- The validation framework for Health Canada eCTD submissions is redesigned to provide agency-driven filtering of criteria and optimized PDF file processing that improves the overall performance of Health Canada eCTD submission validation. This helps to expedite future updates for new validation criteria releases from the Health Canada eCTD Validation Rules version 4.4.

Details: Ennov InSight Validator 5.1 CHF 8

The Ennov InSight Validator 5.1 Release Notes contain information about updated files, new functionality, and any open issues and workarounds in Ennov InSight Validator 5.1.

This certified hotfix is an interim fix to issues that have been reported. It is not a general release of Ennov InSight Validator

This certified hotfix is supplied as a **.zip** file containing the following component(s) in a cumulative package set:

Component	Version	Customize
InSight Validator-Setup.exe	5.1.0.110	No

Enhancements: Ennov InSight Validator 5.1 CHF 8

Requested new features and enhancements are included in each release. The items are listed in descending order by their tracking numbers. Customer case numbers that were recorded when the enhancements were requested are included in brackets [#####] following the tracking number.

The Ennov InSight Validator 5.1 CHF includes the following enhancements:

Issue	Description
N/A	CA Region: The validation framework for Health Canada eCTD submissions is redesigned to provide agency driven filtering of criteria and optimized PDF file processing that improves the overall performance of Health Canada eCTD submission validation. This helps to expedite future updates for new validation criteria releases from the Health Canada eCTD Validation Rules version 4.4.
839; [00060354, 00064322]	<p>Following on the previous modification made for issue 831 (see <i>Resolved Issues: Ennov InSight Validator 5.1 CHF 6</i>), Ennov InSight Validator 5.1 CHF 8 enhances tracking tables for the 11.7 criteria for EU submissions. With this release:</p> <ul style="list-style-type: none"> Any modified leaf WITHOUT a valid modified leaf attribute will Fail. Any modified leaf WITH a valid modified leaf attribute will Pass. <p>A tracking table WITH a modified leaf and WITH a valid modified leaf attribute will pass and will produce the following Best Practice warning: "You have referenced the Tracking Table with operation attribute of 'delete/append/remove'. It is recommended that the tracking table is always provided with the operation attribute of 'new', due to national sequences in MRP/DCP."</p>
838; [00063937]	CA Region: Ennov InSight Validator 5.1 CHF 8 supports the new Health Canada version 4.4 of the "non-eCTD electronic-only" format validation rules.

Issue	Description
N/A	CH region: Ennov InSight Validator 5.1 CHF 8 supports the updated CH Module 1 Specification for eCTD Version 1.5.
N/A	CN Region: Ennov InSight Validator 5.1 CHF 8 supports the new China NMPA eCTD Specification Version 1.0, validation criteria 1.0.
N/A	GCC: The validation framework for GCC NeeS submissions is redesigned to provide agency driven filtering of criteria and optimized PDF file processing that improves the overall performance of GCC NeeS submission validation. This helps to expedite future updates for new validation criteria releases from the GCC NeeS Validation Criteria version 1.2.
N/A	JO region: Ennov InSight Validator 5.1 CHF 8 supports the new Jordan Module 1 eCTD Specification Version 1.1, validation criteria 1.1.
N/A	US Region: Ennov InSight Validator 5.1 CHF 8 supports the new US FDA v3.8 eCTD validation criteria.
N/A	ZA region: Ennov InSight Validator 5.1 CHF 8 supports the updated South African Module 1 Specification for eCTD Version 3.0.

Resolved Issues: Ennov InSight Validator 5.1 CHF 8

The following issues that were reported to Technical Support have been resolved. Issues are listed in descending order by their tracking numbers. Customer incident numbers that were recorded when the issues were reported are included in brackets [#####] following the tracking number.

Name	Description
846; [INC0034011]	When running a validation for a large US submission (approximately 125GB), the ".pdf' is corrupt or unreadable" error showed for several documents. This issue is resolved with an updated third party library, and the USA 3102 criterion status is Pass.
843; [INC0017176]	When a GCC submission with broken links was run, the appropriate criteria passed instead of failing. This issue is resolved. Ennov InSight Validator defines the broken links and displays the appropriate status.
842; [INC0013626, INC0014874]	For US submissions: When validating a promotional labeling submission, a validation error 7 appeared stating that form 356h was missing and the criterion failed. A promotional labeling submission requires form 2253, not 356h. This issue is resolved.
837; [00064401]	Ennov InSight Validator 5.1 CHF 7 incorrectly passed the B47 criterion when JavaScript content was present in the PDF file from the Health Canada (HC 4.4) submission. This issue is resolved with the addition of a JavaScript content check in Ennov InSight Validator 5.1 CHF 8.

Chapter 13. Ennov InSight Validator 5.1 CHF 7 Release Notes

Details: Ennov InSight Validator 5.1 CHF 7

The Ennov InSight Validator 5.1 Release Notes contain information about updated files, new functionality, and any open issues and workarounds in Ennov InSight Validator 5.1.

This certified hotfix is an interim fix to issues that have been reported. It is not a general release of Ennov InSight Validator

This certified hotfix is supplied as a .zip file containing the following component(s) in a cumulative package set:

Component	Version	Customize
InSight Validator-Setup.exe	5.1.0.085	No

Enhancements: Ennov InSight Validator 5.1 CHF 7

Requested new features and enhancements are included in each release. The items are listed in descending order by their tracking numbers. Customer case numbers that were recorded when the enhancements were requested are included in brackets [#####] following the tracking number.

The Ennov InSight Validator 5.1 CHF includes the following enhancements:

Issue	Description
N/A	JO region: Ennov InSight Validator supports the new Jordan Module 1 eCTD Specification Version 1.0.2, validation criteria is 1.0.
N/A	CA Region: Ennov InSight Validator supports the updated Health Canada Version 4.4 of the eCTD validation rules. <ul style="list-style-type: none">• Revised criteria: A09, F25, F26, G34, I02• New criteria: F27

Chapter 14. Ennov InSight Validator 5.1 CHF 6 Release Notes

Details: Ennov InSight Validator 5.1 CHF 6

The Ennov InSight Validator 5.1 Release Notes contain information about updated files, new functionality, and any open issues and workarounds in Ennov InSight Validator 5.1.

This certified hotfix is an interim fix to issues that have been reported. It is not a general release of Ennov InSight Validator

This certified hotfix is supplied as a .zip file containing the following component(s) in a cumulative package set:

Component	Version	Customize
InSight Validator-Setup.exe	5.1.0.080	No

Enhancements: Ennov InSight Validator 5.1 CHF 6

Requested new features and enhancements are included in each release. The items are listed in descending order by their tracking numbers. Customer case numbers that were recorded when the enhancements were requested are included in brackets [#####] following the tracking number.

The Ennov InSight Validator 5.1 CHF includes the following enhancements:

Issue	Description
N/A	CH region: Ennov InSight Validator supports the updated Swiss Module 1 Specification for eCTD Version 1.4 validation criteria.
N/A	CA Region: Ennov InSight Validator supports the new Health Canada version 4.4 of the eCTD validation rules. <ul style="list-style-type: none">• Revised criteria: A06b, B01, B32, B38, F22, G03, G04, G06, G07, G08, H08.• New criteria: A09, B45, B46, B47, F24, F25, F26, G33, G34, I01, I02, I03,I04,I05, I06
N/A ;	CA Region: For the new section, <i>I: Regulatory Enrollment Process (REP)</i> , the following criteria are added: <ul style="list-style-type: none">• I01 - Corrupt xml file. An XML file will be reported as corrupt if the file cannot be opened because the file is damaged.• I02 - Missing Regulatory Transaction (RT) XML file. Checks the 1.2.1 Application Forms node. Generates an error if the RT file is missing.

Issue	Description
	<ul style="list-style-type: none"> • I03 - Placement of the Regulatory Transaction (RT) and Product Information (PI) xml file. Verifies the placement of the RT and PI xml files. Generates error if they are placed in a node other than 1.2.1 Application Forms. • I04 - Presence of the Submission Application form (3011). Checks the 1.2.1 Application Forms node. Generates a warning if in addition to the RT xml file there is a 3011 form (hc-sc-3011-en.pdf or hc-sc-3011-fr.pdf). • I05 - Presence of other xml files in the Application Forms node. Checks the 1.2.1 Application Forms node. Generates an error if in addition to the RT xml and/or PI xml file there are other xml files. • I06 - Comparison of the RT file with the top level folder (Dossier ID folder). Compares the value in the Dossier ID field in the RT file with the top level folder (eXXXXXX).
832;	CA Region: Ennov InSight Validator will now have the F26 criterion with the severity <code>Warning</code> , if the Section 1.2.7 does not have a node extension.
814; [00057594]	CA Region: Ennov InSight Validator will now have the G34 criterion with the severity <code>Error</code> , if the Section 3.2 R does not have a node extension (sections 3.2.R.1, 3.2.R.2, 3.2.R.3 and 3.2.R.4).

Resolved Issues: Ennov InSight Validator 5.1 CHF 6

The following issues that were reported to Technical Support have been resolved. Issues are listed in descending order by their tracking numbers. Customer incident numbers that were recorded when the issues were reported are included in brackets [#####] following the tracking number.

Name	Description
833; [00060614]	When validating a US submission where the sequence number and the submission ID did not match, the 2025 criterion passed. This issue is resolved. If the sequence number and the submission ID do not match, the 2025 criterion fails.
831; [00060354]	For EU submissions, the 11.7 criterion passed when the tracking table leaf had the "replace/append/delete" operation value in eu-regional.xml . This issue is resolved. The "replace/append/delete" operation value criterion fails, and the "new" operation value criterion passes.
830; [00059936, 00060336]	US region: When validating an Annual Report Filing / Report type submission with FDA Form 2252 properly included under m1-1-forms and selecting the General section to be validated, Ennov InSight Validator displayed the status: High - Form 356h is not included for the application '021753' under the 7 criterion. This issue is resolved.
829; [00059990]	US region: When validating US 3.3 submissions, Ennov InSight Validator incorrectly flagged the 2041 criterion with the Medium status instead of Pass when the combination of Submission Type/Submission Sub Type was fdast 4 (Labeling Supplement)/ fdasst5 (Resubmission). The xml element <code><supplement-effective-date-type></code> was incorrectly flagged as missing. This issue is resolved. With Ennov

Name	Description
	<p>InSight Validator 5.1 CHF 6, the validation fails and the Medium status is displayed for the 2041 criterion for the following Submission Type/Submission SubType combinations only:</p> <ul style="list-style-type: none"> • fdast2 (Efficacy Supplement)/fdasst3 (Application) • fdast3 (Chemistry Manufacturing Controls Supplement)/ fdasst3 (Application) • fdast4 (Labeling Supplement)/fdasst3 (Application)
804; [00056296]	<p>A US submission with the submission ID of '0000' was not flagged as the incorrect one in Ennov InSight Validator 5.1 CHF 6. This issue is resolved. If the submission ID is '0000', the 2025 criterion fails.</p>

Chapter 15. Ennov InSight Validator 5.1 CHF 5 Release Notes

Details: Ennov InSight Validator 5.1 CHF 5

The Ennov InSight Validator 5.1 Release Notes contain information about updated files, new functionality, and any open issues and workarounds in Ennov InSight Validator 5.1.

This certified hotfix is an interim fix to issues that have been reported. It is not a general release of Ennov InSight Validator

This certified hotfix is supplied as a .zip file containing the following component(s) in a cumulative package set:

Component	Version	Customize
InSight Validator-Setup.exe	5.1.0.067	No

Enhancements: Ennov InSight Validator 5.1 CHF 5

Requested new features and enhancements are included in each release. The items are listed in descending order by their tracking numbers. Customer case numbers that were recorded when the enhancements were requested are included in brackets [#####] following the tracking number.

The Ennov InSight Validator 5.1 CHF includes the following enhancements:

Is-sue	Description
N/A	US region: Ennov InSight Validator supports the new US FDA v3.7 eCTD validation criteria.
828	US region: Ennov InSight Validator supports the SSL Protocols/Cipher Suites version TLS 1.1 or higher, as specified by the US FDA.
822	US region: According to US FDA, the effective date for the criteria 1734-1737 and 2024-2025 is yet to be determined and therefore can be ignored for validation. The new option Enable TBD Criteria under Preferences > US can be used to include or exclude the criteria 1734-1737 and 2024-2025 from validation. By default, these criteria are included. To actuate the changes, the submission needs to be re-loaded.

Resolved Issues: Ennov InSight Validator 5.1 CHF 5

The following issues that were reported to Technical Support have been resolved. Issues are listed in descending order by their tracking numbers. Customer incident numbers that were recorded when the issues were reported are included in brackets [#####] following the tracking number.

Name	Description
824; [00059021]	AU region: A replaced leaf in the section 1.3.3.1 resulted in an error during validation. This issue is resolved.
820; [00056903]	US region: Ennov InSight Validator failed submissions under the criterion 1323: "No file for leaf element" even when the files were in external applications. This issue is resolved.
815; [00057718]	After validating a submission of considerable size, clicking on Full Report resulted in an error. This issue is resolved.

Chapter 16. Ennov InSight Validator 5.1 CHF 4 Release Notes

Details: Ennov InSight Validator 5.1 CHF 4

The Ennov InSight Validator 5.1 Release Notes contain information about updated files, new functionality, and any open issues and workarounds in Ennov InSight Validator 5.1.

This certified hotfix is an interim fix to issues that have been reported. It is not a general release of Ennov InSight Validator

This certified hotfix is supplied as a .zip file containing the following component(s) in a cumulative package set:

Component	Version	Cus- tomize
InSight Validator-Setup.exe	5.1.0.061	No

Enhancements: Ennov InSight Validator 5.1 CHF 4

Requested new features and enhancements are included in each release. The items are listed in descending order by their tracking numbers. Customer case numbers that were recorded when the enhancements were requested are included in brackets [#####] following the tracking number.

The Ennov InSight Validator 5.1 CHF includes the following enhancements:

Issue	Description
826	AU region: Ennov InSight Validator supports the updated version 2.1 document matrix for the sections m1-3-1-3, m1-3-2-3, and m1-3-3-3.
800; [00054460]	CA region: Ennov InSight Validator will now pass the final validation even if the criteria with severity <code>warning</code> or <code>Info</code> fails, as long as the criteria with the severity <code>Error</code> passes. The report preferences that were made in the <code>usersettings.xml</code> file can now be done in the UI under Preferences > User Preferences > Error Only Report Preferences. This settings is applicable for all regions.

Resolved Issues: Ennov InSight Validator 5.1 CHF 4

The following issues that were reported to Technical Support have been resolved. Issues are listed in descending order by their tracking numbers. Customer incident numbers that were recorded when the issues were reported are included in brackets [#####] following the tracking number.

Name	Description
823; [00058704]	Ennov InSight Validator failed submissions that were in acceptable format under the criterion 9.7. This issue is resolved.
818	Review: After loading a revised index or regional xml file in the <i>Review</i> tab, making changes to a submission and clicking the Save button resulted in an error. This issue is resolved.
812; [00057125]	<p>The following issues are resolved in this release:</p> <ul style="list-style-type: none"> • Submissions with links that were not set to inherit zoom were passed under the criterion 16.BP4. • Submissions with corrupted XFA forms were passed under the criterion 16.5.
810	Review: Changing the value of xmlns:xlink resulted in the change of values for xlink:href and xlink:type elements. This issue is resolved.
806	Ennov InSight Validator failed submissions that were in acceptable formats and also satisfied the ICH and EU specifications for folder structure and names under the criteria 15.1 and 15.BP2. This issue is resolved.
803	On computers without the Arial Narrow font type installed, the complete text of the message was not displayed entirely on some message windows. This issue is resolved.
802	When a submission was shared without a parent folder, opening Ennov InSight Validator resulted in an unhandled exception error. This issue is resolved.

Chapter 17. Ennov InSight Validator 5.1 CHF 3 Release Notes

Details: Ennov InSight Validator 5.1 CHF 3

The Ennov InSight Validator 5.1 Release Notes contain information about updated files, new functionality, and any open issues and workarounds in Ennov InSight Validator 5.1.

This certified hotfix is an interim fix to issues that have been reported. It is not a general release of Ennov InSight Validator

This certified hotfix is supplied as a **.zip** file containing the following component(s) in a cumulative package set:

Component	Version	Cus-tomize
InSight Validator-Set-up.exe	5.1.0.053	No

Enhancements: Ennov InSight Validator 5.1 CHF 3

The Ennov InSight Validator 5.1 CHF includes the following enhancements:

EU EMA Support

Ennov InSight Validator 5.1 CHF 3 includes support for EU EMA updated eCTD v7.1 and NeeS v4.3 validation criteria.

AUS TGA Support

Ennov InSight Validator 5.1 CHF 3 includes support for Australian TGA updated v3.1 eCTD and NeeS validation criteria

US FDA Support

Ennov InSight Validator 5.1 CHF 3 includes support for US STF stylesheet version 2.3.

Resolved Issues: Ennov InSight Validator 5.1 CHF 3

The following issues that were reported to Technical Support have been resolved. Issues are listed in descending order by their tracking numbers. Customer incident numbers that were recorded when the issues were reported are included in brackets [#####] following the tracking number.

Issue	Description
816	Ennov InSight Validator CHF 3 includes support for US STF stylesheet version 2.3.
813; [00056685]	Ennov InSight Validator failed submissions that had the magnification already set to default under the criterion 5045. This issue is resolved.

Issue	Description
541; [00036828]	Ennov InSight Validator failed submissions that had the Page Layout already set to default under the criterion 5045. This issue is found to be not reproducible in Ennov InSight Validator 5.1 CHF 3.

Chapter 18. Ennov InSight Validator 5.1 CHF 2 Release Notes

Details: Ennov InSight Validator 5.1 CHF 2

The 5.1 Release Notes contain information about updated files, new functionality, and any open issues and workarounds in Ennov InSight Validator 5.1.

This certified hotfix is an interim fix to issues that have been reported. It is not a general release of Ennov InSight Validator

This certified hotfix is supplied as a .zip file containing the following component(s) in a cumulative package set:

Component	Version	Cus-tomize
InSight Validator-Set-up.exe	5.1.0.045	No

Enhancements: Ennov InSight Validator 5.1 CHF 2

The Ennov InSight Validator 5.1 CHF includes the following enhancements:

Health Canada Support

Ennov InSight Validator 5.1 CHF 2 includes support for Health Canada updated eCTD validation criteria v4.3.

Resolved Issues: Ennov InSight Validator 5.1 CHF 2

The following issues that were reported to Technical Support have been resolved. Issues are listed in descending order by their tracking numbers. Customer incident numbers that were recorded when the issues were reported are included in brackets [#####] following the tracking number.

Issue	Description
811; [00057037, 00057014]	Submissions that failed with the status High for a criterion was recorded as passed in the Full report. This issue is resolved.
809; [00056926, 00056917]	US region: Valid bookmarks were incorrectly flagged as "inactive" under criterion 5110 – Inactive Bookmark. This issue is resolved.
808; [00056702]	Submissions containing files with the extension .doc and .docx in the section M1-16 were failed during validation. These file types are now passed according to the File Type Specifications version 3.0.

Issue	Description
805	When a PDF file was opened in the Viewer tab, the beginning and the end of the PDF file was not fully displayed. This issue is resolved.
389	GCC Nees: Ennov InSight Validator failed submissions under for the criterion "3.7: For Modules 1-5: The folder structure and names must follow the GCC or ICH defined structure and names." for the files names which complied to the ICH naming convention. This issue has been resolved.

Chapter 19. Ennov InSight Validator 5.1 CHF 1 Release Notes

Details: Ennov InSight Validator 5.1 CHF 1

The Ennov InSight Validator 5.1 Release Notes contain information about updated files, new functionality, and any open issues and workarounds in Ennov InSight Validator 5.1.

This certified hotfix is an interim fix to issues that have been reported. It is not a general release of Ennov InSight Validator

This certified hotfix is supplied as a **.zip** file containing the following component(s) in a cumulative package set:

Component	Version	Cus- tomize
InSight Validator-Set-up.exe	5.1.0.032	No

Resolved Issues: Ennov InSight Validator 5.1 CHF 1

The following issues that were reported to Technical Support have been resolved. Issues are listed in descending order by their tracking numbers. Customer incident numbers that were recorded when the issues were reported are included in brackets [#####] following the tracking number.

Name	Description
799; [00054920]	Ennov InSight Validator did not fail submissions under the criterion c07 when the util folder was present under the M3 folder. This issue is resolved.
796; [00053865]	When the validation criteria <i>Validate leaves and Leaf attributes</i> was selected, Ennov InSight Validator displayed an Out of Memory error. This issue is resolved.
792	ICH eCTD: Ennov InSight Validator failed to save the changes made to the option Max. Leaf Title Length. This issue can be resolved by specifying a new leaf title length in the filefoldersettings.xml file. Note: The ability to specify the leaf title length in the filefoldersettings.xml file is not applicable to US FDA submissions. Note: The option Max. Leaf Title Length on the ICH eCTD tab on the Preferences window is no longer available.
776; [00050034]	Review: Hyperlinks with their destination set to external pages failed to resolve. This issue is resolved.
546	Clicking a link in a PDF document that contained a large number of pages and was opened in the Document Viewer failed to resolve to the destination page. This issue is resolved.

Chapter 20. Ennov InSight Validator 5.1 Release Notes

Ennov InSight Validator 5.1 Release Notes

The Ennov InSight Validator 5.1 Release Notes contain information about updated files, new functionality, and any open issues and workarounds in Validator 5.1.

The Release Notes are identified by internal tracking numbers that are listed in the first column of the tables used to describe the issues. These numbers are used by the Ennov Product Development and Technical Support teams to track known and resolved issues.

The details in these Release Notes supersede all similar details that appear anywhere else in this release of the product or its other documentation.

New in Ennov InSight Validator 5.1

Ennov InSight Validator 5.1 includes enhancements and also addresses prioritized hotfixes and known issues from previous versions. The following enhancements, functional changes, and updates are planned for this release.

Updated Validation Framework for US Submissions

The validation framework for US FDA submissions has been redesigned to provide agency driven filtering of criteria and optimized PDF file processing that improves the overall performance of US FDA submission validation. This will also help to expedite future updates for new validation criteria releases from the US FDA.

Support Discontinuation - Croatia Region

Croatia now follows the EU regional specification module as a result of its accession to the European Union. As a result, Ennov InSight Validator no longer supports the validation of submissions for the Croatia region.

List of Enhancements: Ennov InSight Validator 5.1

The following table provides details of the enhancements in Ennov InSight Validator 5.1:

Issue	Description
676	Ennov InSight Validator now includes an enhanced file browser that navigates directly to the UNC path.

Resolved Issues: Ennov InSight Validator 5.1

The following table provides details of the enhancements and issues resolved in Ennov InSight Validator 5.1:

Issues are listed in descending order by their tracking numbers. Customer incident numbers that were recorded when the issues were reported are included in brackets [#####] following the tracking number.

Issue	Description
794	US region: For US submissions, the option to specify the file extension for validation has been removed. It will now not be possible to validate US submissions against user defined file extensions.
793; [00054368]	US region: Ennov InSight Validator failed submissions under the criterion 1306 when there was a difference in the file path and xml xlink:href letter case. This issue is resolved.
790; [00052050]	Ennov InSight Validator froze when validating PDF documents which contained web links with non-printable characters. This issue is resolved.
788; [00051337]	AU region: Ennov InSight Validator failed submissions under the criterion 6.12: "Hyperlinks to other external destinations (not web or email) are not allowed". This issue is resolved.
787	For US region: US FDA submissions with a large number of sequences being validated over a network location were taking considerably longer to complete when compared with local file system validation. Subject to network related factors, performance has been improved.
786; [00052239]	When recalculating checksums, the values in the regional.xml file inadvertently changed. This issue is resolved.
784; [00051673]	GCC region (NeeS): Ennov InSight Validator failed submissions that had correct folder structure and folder names under the criteria 3.7 and 3.8. This issue is resolved.
783; [00051156]	EU region: Ennov InSight Validator failed submissions under the criterion 11.10 when leafs replaced in section 1.2 had the country attribute "emea" instead of "ema". According to the Harmonised Technical Guidance for eCTD Submissions in the EU (v4.0) guidelines, leafs with the country attribute 'ema' or 'emea' are valid. This issue is resolved.
782; [00035215]	US region: For submissions with PDF security enabled form 3676, Ennov InSight Validator failed these submissions under the criteria 5040 and 5020. According to FDA guidelines, PDF security enabled form 3676 must be exempt under the criteria 5040 and 5020. This issue is resolved.
769	ZA region: Some element names on the Submission pane were followed by unexpected characters, such as question marks or equal signs, instead of a colon. This issue is resolved.
767; [00048324]	CA region: Ennov InSight Validator failed submissions that had correct sequence descriptions under the criterion F09. This issue is resolved.
753; [00046504]	US region: Submissions without STF files in sections 5.3.6 and 5.3.7 are considered valid according to the FDA guidelines and therefore such submissions are now passed by Ennov InSight Validator.
744	Canada: Validation: Criterion C03 did not check the operation status for an initial submission and displayed an uninformative error description. This issue is resolved.
729	HC region: For the criterion G16, Ennov InSight Validator validated submissions for the modules m2-m5 while the validation as a prerequisite is limited to m1 module according to criterion G16. This issue has been resolved.

Issue	Description
725	HC region: Ennov InSight Validator failed submissions under the criteria A02 and C06 when they complied with the requirements of these criteria. This issue is resolved.
722	Validation number inaccuracies in the Validation window have been fixed in this release.
683	EU NeeS: Ennov InSight Validator failed submissions under the criterion 1.4 - "If Module TOC files are present, each and every module folder (/m1, /m2, etc.) contains the correctly named Module TOC file", although no module TOCs were present in the submissions. This issue is resolved.
679; [00042852]	Ennov InSight Validator should display a warning when both an STF and a Node Extension are used in a Health Canada submission, when only one or the other is permitted. This issue is resolved.
675	The Errors Only report displayed only high severity errors, when it should display all errors. This issue is resolved
659	US region: The error message displayed when a submission failed under the criterion 1130 was incorrect. This issue has been resolved.
643	Review: When the Ennov InSight Validator window was changed to a size smaller than the full size, clicking on the Recalculate button reset the window to full size instead of retaining the previously set size. This issue is resolved.
606	Unnecessary validation criteria for a US 2.01 submission appeared on the Validation Results tab when a US 3.3 submission was opened. This issue is resolved.
594	After modifying the report location path under User Preferences, if you selected another tab and then clicked OK, the changes made to the report location were not saved. This issue is resolved.
593	Ennov InSight Validator could not open and validate submissions that included an invalid DTD version attribute in a regional XML file. This issue is resolved.
577	US region, DTD 3.3 version: The submission information under Selected Submission Details was displayed in a table instead of in a list. This issue is resolved.
570; [00039927, 00051403, 00052050]	Slow performance issues were evident when trying to load and validate large submissions when using a network connection between distinct geographical locations. This issue has been resolved.
562	After making changes in the Preferences window and clicking on "No" in the confirmation message, the "Reset" and "Reset All" options failed to restore the original values. This issue is resolved.
538	EU NeeS: Validation did not report a failure when Bookmarks present in the main CTD TOC file were not functioning correctly. This issue is resolved.
517	Croatia now follows the EU regional specification module as a result of its accession to EU. Therefore, Ennov InSight Validator no longer supports the validation of Croatia submissions.

Licensing

Validator is a desktop product that utilizes different user licenses to control access to the validation and review features. The licenses in version of Validator 5.1 are not associated with different costs, so you can request the different license types based purely on your user requirements.

It is important to determine whether you will give all of your users complete access to the system or perhaps restrict some users by using a different user license that provides more basic access to the system. All license options provide full access to the validation features but provide different access to the reviewing features.

The license options available are as follows:

License Type	Description
Validation Only	<p>This license is for users who will require access to the validation features only, and will not need to access the Review features.</p> <p>This may be helpful for existing InSight GateKeeper customers who want to restrict software validation and training to the existing features available in InSight GateKeeper.</p>
Validation and Review	<p>This license provides access to all of the validation features previously available in InSight GateKeeper. The user will also have the ability to review the sequence view, see envelope and document metadata, and open the documents in a document viewer to view the PDF content.</p> <p>Users will not be able to edit any metadata using Validator, and will not be able to recalculate checksums.</p>
Validation Review and Edit	<p>This license provides access to all of the validation features previously available in InSight GateKeeper. The user will also have the ability to review the sequence view, see envelope and document metadata, and open the documents in a document viewer to view the PDF content.</p> <p>In addition, users will be able to edit envelope and document metadata and recalculate checksums.</p>

Obtaining licenses

After determining your license requirements, contact Technical Support to initiate the licensing process.

Chapter 21. Known Issues: Ennov InSight Validator 5.1

The following issues were known at the time this document was published.

Issue	Description
DE32211	Health Canada I11 criterion fails for NeeS and eCTD submissions due to updated software version.
855	Systems without Arial Unicode MS font installed can adversely affect the way Unicode symbols are shown in the <i>Error Only Report</i> and the <i>Full Report</i> . As a workaround, we recommend that you obtain Arial Unicode MS and install it using <i>Font Settings</i> in Windows.
853	CA region: eCTD submissions that contain scanned forms could fail if they contain: <ul data-bbox="695 793 1393 947" style="list-style-type: none">• An owner password: a warning is displayed for the B32 criteria• Dynamic content or 3D content: an error is displayed for the B47 criteria• Java script: an error is displayed for the B48 criteria
849	For CH submissions of version 1.3 and 1.4: after performing the Max. File Size changes in the Preferences > ICH eCTD , the 15.BP1 criterion gets the Best Practice status instead of Pass status.

Chapter 22. Clarification of Behavior: Ennov InSight Validator 5.1

De- fect id	Description
N/A	For EU submissions, validation skips keywords for the criterion 16BP.11. As this is a best practice, no pass or fail status is displayed.