



PegmaPharm
eCTD builder

The smart choice
for regulatory
submissions

eCTD

NeeS

pCTD

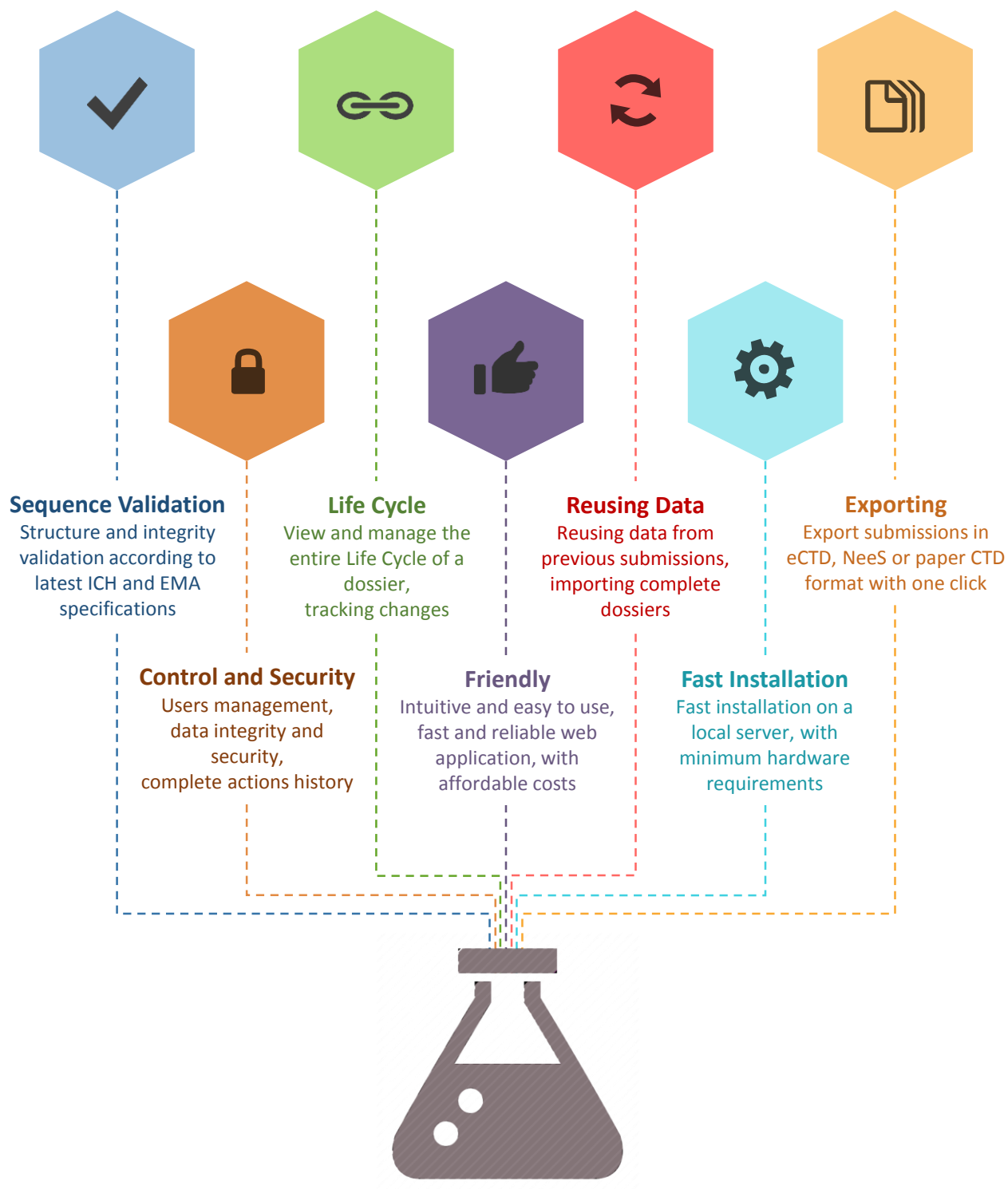
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PegmaPharm

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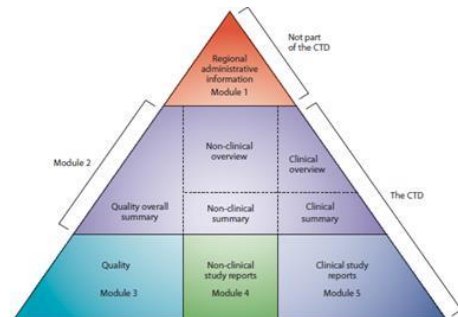




System Purpose and Applicability

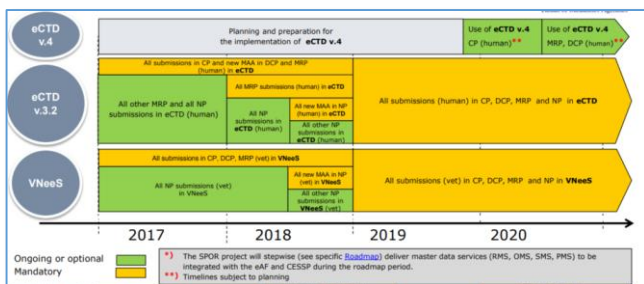
What is eCTD

Electronic Common Technical Document (eCTD) is an interface dedicated to the pharmaceutical industry for the storage and transmission of regulatory information. Content is based on the Common Technical Document (CTD) format and regulation, developed by **International Conference on Harmonisation (ICH)** Multidisciplinary Group 2 Expert Working Group.



Roadmap

The E.U. and **European Medicines Agency (EMA)** began accepting eCTD submissions in 2003. In February 2015, the EMA announced that it would no longer accept paper application forms for "human and veterinary centralised procedure applications" starting from July 2015 and that all electronic application forms would have to be eCTD by January 2016.



[EMA roadmap for eCTD and VNeS](#)

The **roadmap** published by EMA reveals the mid-term target to not accept any more paper application forms or NeeS for human products starting from **January 2019**.

Also, from **July 2018**, all MAAs for National Procedures should be submitted in **eCTD** format (V.3.3.2).

Our Solution

PegmaPharm offers the best price-quality ratio on a standard software system for pharmaceutical manufacturers as well as regulatory consultants to build, validate, publish, manage and review **electronic submissions**.

It complies with **eCTD**, **NeeS**, **VNeS** and paper submissions according to latest specifications for all EU countries.

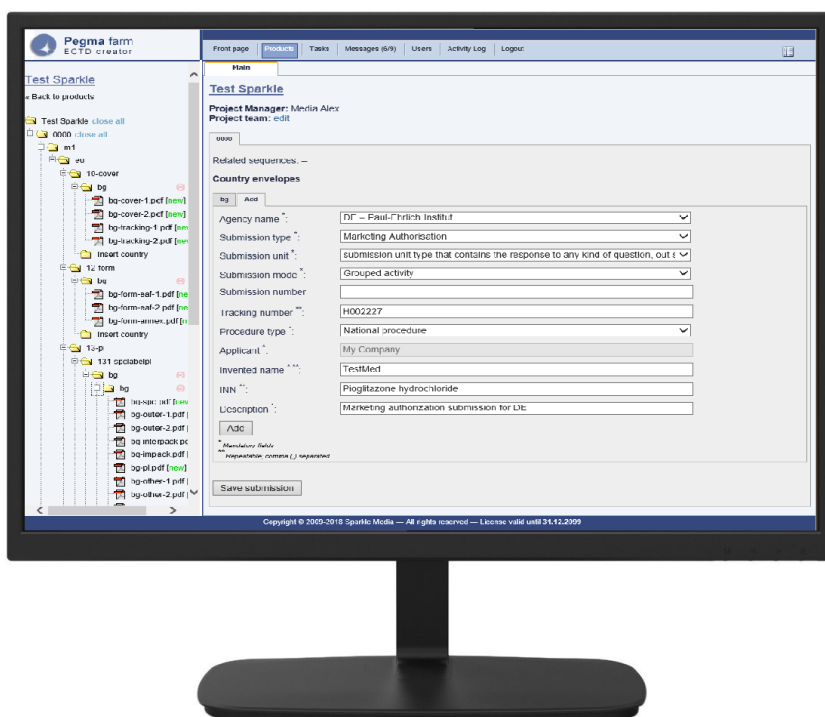
In order to minimise the human effort, besides standard validation, life cycle management, creating, managing and exporting eCTD dossiers, PegmaPharm also provides a set of modules and functionalities meant to improve **organization**, **communication** and **data integrity**.



Why PegmaPharm

From a Customer perspective, **PegmaPharm** comes with a set of features and functionalities granting a very low price-performance ratio:

- ✓ **Security** and data privacy
- ✓ **User friendly** visual interface
- ✓ Export dossiers in **eCTD** and **NeeS** format
- ✓ Validated against **Lorenz Validator**
- ✓ Constantly **updated** based on ICH and EMA specifications
- ✓ System **users and rights** management
- ✓ Detailed step-by-step **supervision** of dossiers evolution
- ✓ **Life Cycle** Management
- ✓ **Import** submissions generated with other applications
- ✓ **Re-using** data from previous submissions
- ✓ Complete **actions history**
- ✓ Built-in **communication** between users
- ✓ **Fast and simple** implementation process
- ✓ **Affordable** price and minimum additional costs
- ✓ **Web application** – accessible from any location, based on security access credentials





eCTD submissions and files management

- ✓ Create and manage eCTD and NeeS dossiers
- ✓ Add, modify and delete files based on eCTD structure
- ✓ Documents upload, based on validation criteria
- ✓ Multiple documents upload
- ✓ Submission structure and content validation
- ✓ Built-in documents preview

The screenshot displays the Pegma farm eCTD creator interface. The main window shows a tree view of the eCTD structure on the left, including folders like '0001', '0002', '0003', '0004', '0005', 'm1', 'eu', '10-cover', '12-form', '13-pl', '131-apclabelpl', '132-mockup', '133-specimen', '134-consultator', '135-approved', '136-braille', '14-expert', '15-specific', and '16-environment'. The central panel shows the 'Main' page with 'Project Manager: John Smith' and 'Project team: edit'. The right panel shows the 'Files in 1.3.1 - SPC, Labelling and Package Leaflet' section, listing files like 'bg-spc.pdf', 'bg-out-1.pdf', 'bg-out-2.pdf', 'bg-impact.pdf', 'bg-pl.pdf', 'bg-other-1.pdf', and 'bg-other-3.pdf'. Below this, there is a 'Files in 1.3.2 - Mock-up' section with files like 'bg-mockup-1.pdf', 'bg-mockup-2.pdf', and 'bg-mockup-3.pdf'. At the bottom, there is a 'Quality Overall Summary' section with a table and text. The table has columns for 'Albionin 5%' and 'Date: 18.03.2008'. The text describes the production facilities of Biotest AG / Biotest GmbH, Landsteinerstr. 5, 63303 Dreieich, Germany. The interface also includes a 'Drop files here to upload' area and a 'Make changes to this document' section with buttons for 'append...', 'replace...', and 'delete'.



Export eCTD and NeeS submissions

Save your sequence and export it to the latest version of eCTD, NeeS or both formats, validated and suitable for online submission.

- ✓ Export sequence to eCTD format – Version 3.2.2
- ✓ Structure and integrity validation
- ✓ Backbone file generation
- ✓ MD5 verification codes generation
- ✓ Export sequence to NeeS format – Version 4.0
- ✓ Ready for eCTD version 4.0

Validated against
Lorenz Validator

eCTD DTD version 3.2

- m1-administrative-information-and-prescribing-information
 - [European Union](#) [new]
- m2-common-technical-document-summaries
 - m2-2-introduction
 - [2.2 Introduction](#) [new]
 - m2-3-quality-overall-summary
 - m2-3-introduction
 - [2.3.1 Introduction](#) [new]
 - m2-3-s-drug-substance [manufacturer: Biotest] [substance: HA]
 - [2.3.S Drug Substance - HA - Biotest](#) [new]
 - m2-3-p-drug-product [manufacturer: Biotest] [product name: Albiomin 5%] [dosage form: Infusion]
 - [2.3.P Drug Product - Albiomin 5%](#) [new]
 - m2-3-a-appendices
 - [2.3.A Appendices](#) [new]
 - m2-3-r-regional-information
 - [2.3.R Regional Information](#) [new]
 - m2-4-nonclinical-overview
 - [2.4 Nonclinical Overview](#) [new]
 - m2-5-clinical-overview
 - [2.5 Clinical Overview](#) [new]
 - m2-6-nonclinical-written-article
 - m2-6-1-introduction
 - [2.6.1 Introduction](#)
 - m2-6-2-pharmacology
 - [2.6.2 Pharmacology](#)
 - m2-6-3-pharmacokinetics
 - [2.6.3 Pharmacokinetics](#)
 - m2-6-6-toxicology
 - [2.6.6 Toxicology](#)
 - m2-6-7-toxicology
 - [2.6.7 Toxicology](#)
 - m2-7-clinical-summary
 - m2-7-1-summary-overview
 - [2.7.1 Summary Overview](#)
 - m2-7-2-summary-tables
 - [2.7.2 Summary Tables](#)

Tracking number	123
Procedure type:	National procedure
Applicant:	My Company
Invented name:	Sparkle Drug
INN:	1234
Description:	Sparkle Drug
Envelope options	edit / delete

Document backbone: [Test Sparkle/0000/index.xml](#)

eCTD archive for Test Sparkle 0000 [Download](#) (5.21 MB) / [Remove archive](#)

[Create NEES archive](#)

[Reopen submission](#)



Complete Lifecycle management

View and manage full lifecycle of a dossier, relations between sequences and actions history.

- ✓ Complete actions history on all dossiers
- ✓ Lifecycle viewer
- ✓ History of dossier evolution
- ✓ Tracking changes by sequence
- ✓ Tracking table

Activity Log

Username	Date and time	Document	Sequence	Action	Details
admin	Date: 25.08.2010 Time: 13:28:48	Albumiol	0005	file upload	m3/32-body-data/32p-drug-prod/human-albumin-infusion-bromura/specifications.pdf
admin	Date: 25.08.2010 Time: 13:26:00	Albumiol	0005	file upload	m3/32-body-data/32p-drug-prod/human-albumin-infusion-chloride/analytical-procedures.pdf
admin	Date: 25.08.2010 Time: 13:25:48	Albumiol	0005	file upload	m3/32-body-data/32p-drug-prod/human-albumin-infusion-formula.pdf
admin	Date: 25.08.2010 Time: 13:25:48	Albumiol	0005	file upload	m3/32-body-data/32p-drug-prod/human-albumin-infusion-manuf/manufacturers.pdf
admin	Date: 25.08.2010 Time: 13:25:40	Albumiol	0005	file upload	m3/32-body-data/32p-drug-prod/human-albumin-infusion-dev/pharmaceutical-development.pdf
admin	Date: 25.08.2010 Time: 13:23:41	Albumiol	0005	file upload	m3/32-body-data/32s-drug-sub/ha-biotest/32s7-stab/stab
admin	Date: 25.08.2010 Time: 13:23:41	Albumiol	0005	file upload	m3/32-body-data/32s-drug-sub/ha-biotest/32s7-stab/pos
admin	Date: 25.08.2010 Time: 13:23:41	Albumiol	0005	file upload	m3/32-body-data/32s-drug-sub/ha-biotest/32s7-stab/stability-summary.pdf
admin	Date: 25.08.2010 Time: 13:23:06	Albumiol	0005	file upload	m3/32-body-data/32s-drug-sub/ha-biotest/32s5-ref-stand/reference-standards.pdf
admin	Date: 25.08.2010 Time: 13:22:45	Albumiol	0005	file upload	m2/26-nonclin-sum/pharmkin-written-summary.pdf

Pages: 1 2 3 4 5 6 7 8 9 10 ... [Last]

Filtered by:

User:

Document:

Action:

- File upload
- File remove
- File append
- File replace
- File delete
- New document
- Document save
- Document reopen

Main

ro-cover.pdf...

Information specific to the paper component(s) of the submission:

You will find enclosed to the submission dossier paper copies of the documentation hereafter:

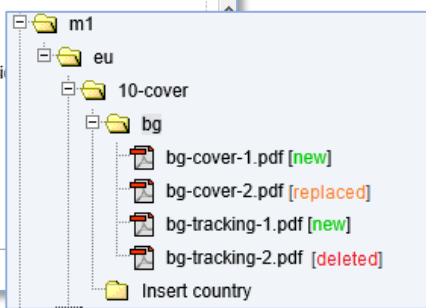
- Module 1: 1 volume, 2 copies

Information specific to the electronic component(s) of the submission:

Type of electronic submission:

eCTD

Make changes to this document:



Sequence	Submission description	CMSs – First Wave					
		RMS DE	AT (CMS-1)	ES (CMS-2)	FR (CMS-3)	SE (CMS-4)	SK (CMS-5)
0005	Country specific information (All)		Feb 09	Feb 09	Feb 09	Feb 09	Feb 09
0004	MRP update sequence	Jan 09	Feb 09	Feb 09	Feb 09	Feb 09	Feb 09
0003	Final agreed National product information	Dec 08	Feb 09	Feb 09	Feb 09	Feb 09	Feb 09
0002	Responses to questions	Sep 08	Feb 09	Feb 09	Feb 09	Feb 09	Feb 09
0001	Validation update	Dec 07	Feb 09	Feb 09	Feb 09	Feb 09	Feb 09
0000	Initial MAA	Dec 07	Feb 09	Feb 09	Feb 09	Feb 09	Feb 09



Submission import and content reuse

Accelerate the process of building a dossier by reusing parts or importing existing submissions.

- ✓ Import existing sequences, generated with any other tool
- ✓ Validate structure and integrity of imported submissions
- ✓ Generate eCTD sequence from CTD structure
- ✓ Multiple files upload
- ✓ Upload entire structure
- ✓ Reusing envelope
- ✓ Reusing files

Document import

Document	Status	Import
New Med	0000.index.xml MD5 checksums failed	
New Med	import succeeded	
New Med	import succeeded	
New Med	import succeeded	
New Med	not started	import
New Med	not started	import

Back

TestMed

TestPill

WonderPill

Add product

Document import

Main

0000

Related sequences: -

Country envelopes

bg Add

Agency name *: -- select --

Submission type *: -- select --

Submission unit *: -- select --

Submission mode *: -- select --

Submission number

Tracking number **:

Procedure type *: -- select --

Applicant *: My Computer

Invented name * **:

INN **:

Description *:

Add

* Mandatory fields
** Repeatable; comma (,) separated

Copy envelope from previous sequence

envelope: -- select -- sequence: -- select --

bg-mockup-1.pdf [new] M1.3 preview / remove

bg-mockup-2.pdf [new] M1.3 preview / remove

bg-mockup-3.pdf [new] test preview / remove

Upload files

Drop files here to upload



Security and Users management

Provide security by managing access rights and limitations on users.

- ✓ **Users administration – create, edit and delete users**
- ✓ **Grant rights and set restrictions on dossiers and modules to users or user groups**
- ✓ **Set a product owner on each dossier**
- ✓ **Secured access on limited areas, based on security credentials**
- ✓ **Complete actions history by user**

Albumiol - Project team

Project Manager: John Smith

Project Participants: Duca Andrei ☒ M1 / ☒ M2 / ☒ M3 / ☒ M4 / ☐ M5 / delete

One User ☒ M1 / ☒ M2 / ☒ M3 / ☐ M4 / ☐ M5 / delete

Some Other ☐ M1 / ☐ M2 / ☐ M3 / ☐ M4 / ☐ M5 / delete

User Two ☒ M1 / ☒ M2 / ☒ M3 / ☒ M4 / ☒ M5 / delete

» Add users to this team

Users

admin - Administrator

andreiduca - Duca Andrei

Petrache Ion - Ion Petrache

test2345 - test test

user - John Smith

user_one - One User

user_three - Some Other

user_two - User Two

Add a new user

User details

Username: Test Sparkle

Password: [click here to change](#)

First name: Sparkle

Last name: Media

Registration date: 2018-03-13 14:01:00

Last login: -

[Click here to edit this user](#)

[Click here to block this user](#)

[Click here to delete this user](#)



Organization and Tasks Management

Tasks, deadlines and traceability for competitive internal organization.

- ✓ Allocate tasks and establish deadlines
- ✓ Follow tasks evolution
- ✓ Cascading tasks
- ✓ Supervising users activity

Users tasks

From	For	Document	Description	Start Date	End Date	Status	Finish
Administrator	User Two	Albumiol - 0004	De terminat modulele M3, M4, M5	2009-12-07	2009-12-13	Finished	
Administrator	User Two	Albumiol - 0004	descriere	2009-12-08	2009-12-21	Waiting confirmation	confirm
Administrator	User Two	Albumiol - 0004	description	2009-12-13	2009-12-29	Deadline exceeded	
Administrator	User Two	Pill - 0000	De terminat modulul M1	2009-12-15	2009-12-25	Deadline exceeded	
Administrator	User Two	Albumiol - 0000	sadas	2009-12-17	2009-12-23	Waiting confirmation	confirm
Administrator	User Two	Albumiol - 0004	blablabla	2009-12-28	2010-01-05	Deadline exceeded	
Administrator	User Two	Albumiol - 0004	sajk			Deadline	
User Two	Some Other	Pill - 0000	You				
Administrator	Andrei Duca	Albumiol - 0000	wor				
Administrator	User One						
Administrator	Andrei Duca						
Administrator	Andrei Duca						

Tasks

My tasks

Calendar view

Users tasks

Create new task

Create new task

Document:

For:

Task description:

Start Date:

End Date:

Documents

Document	Date Created	Current Version	Start Date	Status	Permissions	Project Manager
Albumiol	2009-10-31	0005	2010-01-03	open for work	M1, M2, M3, M4	John Smith
New product	2010-01-03	0000	2010-01-03	open for work	M1, M2, M5	John Smith
Painkiller	2009-11-01	0001	2009-11-08	open for work	M4, M5	Some Other

* You are Project Manager on these documents.

Task list - 9 Apr 2011

Active tasks:

Document	Description	Start Date	End Date
Albumiol - 0000	Sample task	2011-04-07	2011-04-14
Painkiller - 0000	Painkiller task	2011-04-08	2011-04-13

Deadlines:

Document	Description	Start Date	End Date
Albumiol - 0000	work!	2011-01-18	2011-01-20

New tasks:

- No new tasks

Upcoming:

Document	Description	Start Date	End Date
Albumiol - 0000	M1 - finish and check	2011-04-10	2011-04-22

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Communication

Internal communication tools to improve operability.

- ✓ **Internal messenger between application users**
- ✓ **Automatic alerts regarding tasks status**
- ✓ **View changes on sequences by user**

Inbox

No.	From	Subject	Date
1	Ion, Popescu	Sample message	2011-04-09 16:11:57
2	Ion, Popescu	Message	2011-04-09 16:11:42
3	Duca, Andrei	Message 2	2011-04-09 16:08:01
4	Duca, Andrei	Message1	2011-04-09 16:07:41
5	One, User	Ok	2010-01-03 18:52:54

Messages

New message

Inbox

Outbox

New message

To:

Subject:

Duca, Andrei

 min

Message:

to you how all this mistaken idea of denouncing pleasure
was born and I will give you a complete account of the
ound the actual teachings of the great explorer of the truth,
er of human happiness.

Send message