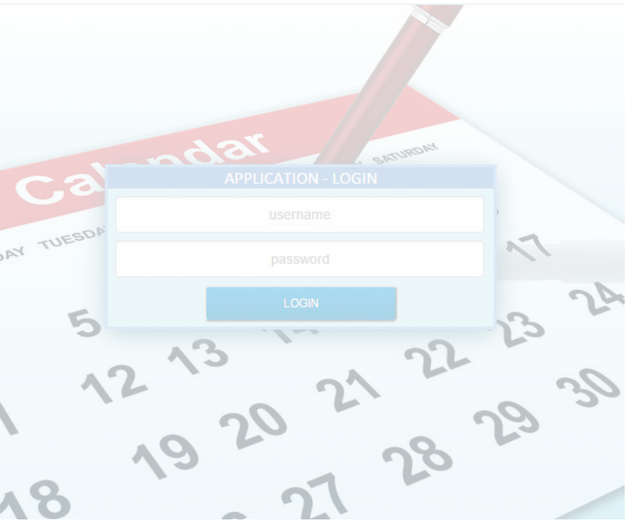
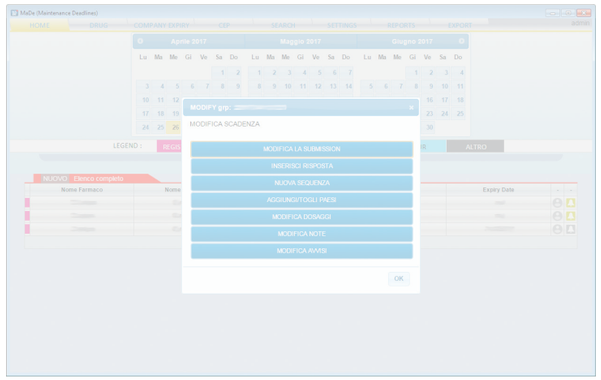
MaDe

Maintenance Deadlines



- Notice by daily email of the approaching deadlines
- Display the deadline dashboard
- WIZARD to help the user in the manual insertion of procedures
- Automatic deadline and warning allocation according to procedure/nation
- Taking charge of the deadline
- Ability to upload documents in the most significant phases

- Reporting
- Export data in excel format
- Direct integration with eCTD-Pharma
- Metadata import from dossier sequences in electronic format



www.grupposasi.com

GRUPPO SASI s.r.l.

via padre reginaldo giuliani, 10/a - 20125 milano
phone number +39 02 87065690 - e-mail: contatti@grupposasi.com

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Maintenance Deadlines

A basic tool for monitoring the process of regulatory procedures

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MaDe • A basic tool for monitoring the process of regulatory procedures

Introduction

The growing need to monitor the process of procedures for the management of the Dossiers and their deadlines, aimed at a better organization of Regulatory Affair department, led us to propose on the market the application ***MaDe*** (Maintenance Deadlines).
The software, developed with the collaboration of specialists with many years of experience in the field of Regulatory Affairs, ensures a management of deadlines and related procedures in full compliance with the requirements established by the legislation allowing the user to focus primarily on the professional content of their role.

Proposal

This software is therefore intended to automate, based on the definition of a few assumptions of a general nature that the user will have to set in the start-up phase, the management of the deadlines of all the steps on which the procedures such as:

- **CENT-DCP-MRP-NAT registrations**
- **Variations (IA, IAin, IB, II, DL, etc.)**
- **New products and services**
- **Sunset (Approval, Launch Date, Latest Release Date)**
- **PSUR**
- **CEP**
- **Company Expiry**
- **Any other type of regulatory activity regulated by a schedule**

At each of these procedures, in correspondence of the procedural steps, it will be possible - where necessary - attach documents in word or pdf format to make it even easier to consult especially in case of deficiency.

The main features are:

- **Notice by email of the approaching deadlines**
  The system, with the approach of a deadline, sends an explanatory email of the actions to be carried out to all users involved in this procedure. The recipients of these mails are those provided in the appropriate section easily updated according to the organizational needs of the Regulatory Office. (The email, by default, is sent to the Head of the Regulatory Office and to those who have registered).
- **Display the deadline dashboard**
  The upper part of the Home Page shows a calendar with the expiry dates of the various procedures, while the lower part provides a summary of the deadlines broken down by type of procedure.
  By clicking on the date highlighted by the calendar, you will see the details of the procedure or procedures expiring on that date.
- **Automatic deadline and warning allocation according to procedure/nation**
  The application provides at the data entry stage of the procedure, in compliance with the provisions of the legislation relating to the nation/ procedure, to schedule automatically the entire sequence of the various expiry dates linked to the subsequent activities to be carried out.
  For example, if I enter Day 0 for a DCP procedure, the application automatically generates the schedule for the next scheduled sequences (Day 70-100-105... etc...) with the relevant deadlines.
- **Reporting and/or data export**
  All the activity of management of the maturities that is carried out using the functions of the system can be consulted at any time through special filters that allow to visualize how much demanded.
  The result of the search can be reproduced both in print and in an excel format to allow the user any operations even outside the application.
- **Integration with eCTD-Pharma**
  If the computer structure of the company is already equipped with our software ***eCTD-Pharma*** is possible, through the functions "Check in the Agency" and "Feedback Agency", interface with the ***MaDe*** application and automatically send all the necessary information to that specific procedure/country.
- **Integration with any other sequence of dossiers in electronic format**
  If the user were in possession of any other electronic publishing tool, it is possible, using the special function of ***MaDe*** that imports the envelope data, to automatically develop the relative procedure for which the user will have only to impute the metadata for the "Approval" or for the "Deficiency".

Conclusions

To finish, we would like to underline that, in the context of the electronic format, ***MaDe*** makes it possible to keep under total control the timetable of all regulatory activities, both by procedure and by country, updating the same with a few clicks and without the commitment of additional resources or the help of complex excel files.
In addition, using pre-set filters, provides a quick and immediate consultation and/ or extraction of the authorization of all drugs, whether they are charged to the Company, marketed by third parties or withdrawn from the market.