A Novel Approach to Pharmaceutical Registration : Registration as a Service

September 27th, 2011

Registration as a Service

During the presentation, I will address the following questions:

- What is Software as a Service (SaaS)?
- What was our initial plan for implementing a registry system as SaaS?
- What issues did we run into?
- What were our responses and decisions to move forward?
- What does the final system architecture look like?
- What are our plans moving forward?

Software as a Service – a definition

Software as a Service - *a software delivery model in which software and its associated data are hosted centrally (typically in the (Internet) cloud) and are typically accessed by users using a thin client, normally using a web browser over the Internet.*

- The application is hosted centrally, so new releases can be put in place without requiring customers to physically install new software.
- The application only has a single configuration, making development testing faster.
- The application vendor has access to all customer data, expediting design and regression testing.
- The solution provider has access to user behavior within the application (usually via web analytics), making it easier to identify areas worthy of improvement.
- Accelerated feature delivery is further enabled by agile software development methodologies. Such methodologies, which have evolved in the mid-1990s, provide a set of software development tools and practices to support frequent software releases.

Why Software as a Service ?

- In 2009, GSK undertook a significant program to simplify it's IT landscape and reduce R&D IT spend.
- This effort resulted in a large program of work to replace or retire products that were expensive to maintain, or posed a risk to the company due to their age.
- The existing GSK registration system was identified as a potential system for replacement.
  - Registration Software was implemented long before current integration standards
  - Support for the product was expensive as it runs on legacy hardware
  - The Chemical cartridge upon which the application was based was being changed to the new Chemaxon standard adopted by GSK.
- As part of the Simplification effort, headcount was also reviewed, and the registrar staff was targeted for a 40% reduction.

The selection Process

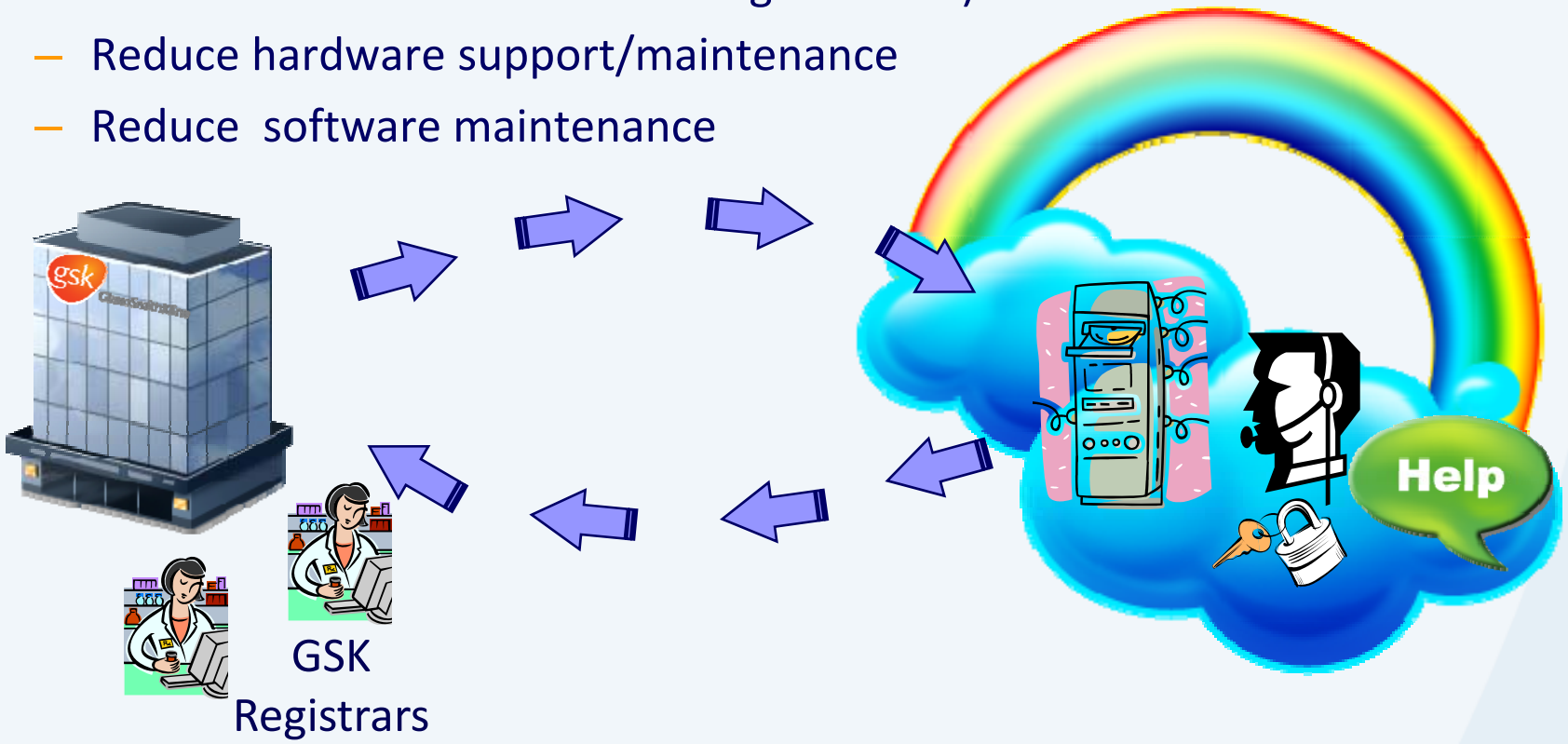
- When the registration systems was targeted for replacement, it was decided Registry would be a good tool on which to attempt a Software as a Service (SaaS) implementation.
- Then the specific IT project team determined the path forward:
  - Existing requirements were reviewed and revised
  - A RFP was prepared and distributed to multiple vendors
  - A paper review of the proposals and interviews were completed
  - An initial vendor was selected
- No other SaaS implementations had been undertaken within GSK R&D IT at that point.

SaaS – Moving into uncharted waters

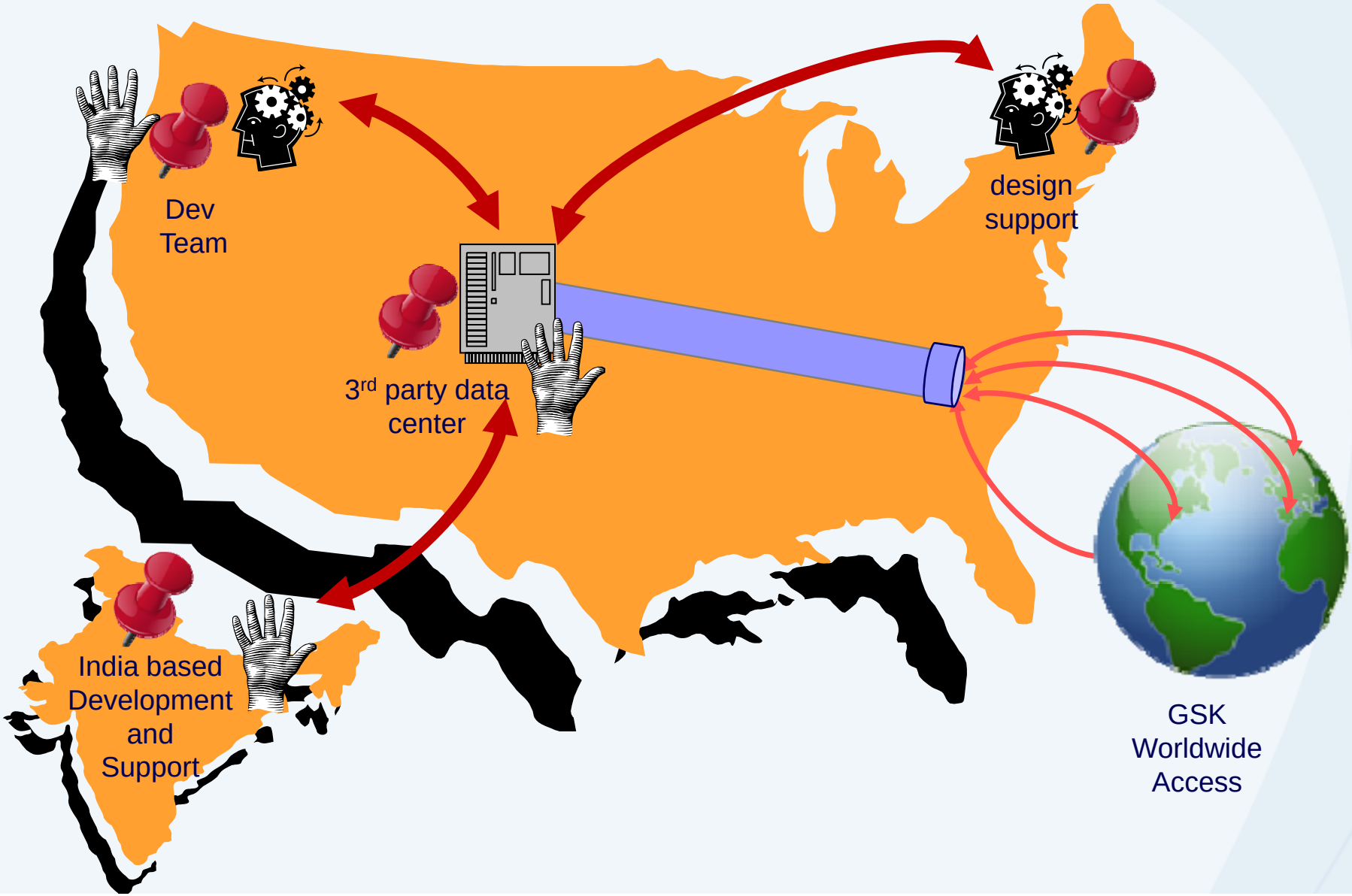
- In late mid 2009 GSK chose a supplier for the Registration as a Service (RaaS) project
- Chemaxon was not the initial choice
  - At that time Chemaxon did not have their own offering for a registration system
- GSK selected a vendor who was re-engineering their existing registration product and was open to a SaaS implementation
  - All support, development, maintenance, help would be managed by the vendor
  - GSK would access the application via the “cloud”
  - GSK would pay a yearly fee for a set number of compounds registered
  - Additional overages would be charged at a sliding fee rate

Our initial idea for Registry as a Service (RaaS)

- The idea behind implementing registry as a service
  - Enable flexibility for moving Registrar resources external to GSK
  - Establish a “Fee for Service” arrangement for Registry (i.e. yearly costs would be based on number of registrations)
  - Reduce hardware support/maintenance
  - Reduce software maintenance



The reality of the initial Implementation Proposal



Working through the Contracts

- The GSK development team started discussing many technical/procedural issues:
  - SAS 70 compliance
  - Software Development Lifecycle Approach
  - Security
  - Support Plans
  - Liability

The Liability Issue

- One topic that the GSK team had not fully considered prior to starting the project was the area of liability
  - How do you put a value on your entire compound collection?
  - When are you sure that the security model is adequate to protect it?
  - How do you get a vendor to insure the value you've assigned?

- Although the initial pricing proposal for a SaaS delivery of a registration service was quite reasonable, it did not cover liability insurance costs for any loss of IP.

- Once these costs were factored in, it became clear that the total cost would be much greater.

An Alternate Approach

- Since the liability issue was challenging the success of the project, the GSK team began to look at alternatives to the existing proposal:
  - GSK had implemented JChem and switched over many of our internal web services
  - We had developed several new applications (Helium) with ChemAxon products and support and had developed a good working relationship with Chemaxon
  - The GSK technical team started investigating development of a registration system based on the Chemaxon tools
- In three months the developers had produced a working prototype and the GSK team saw real potential in the approach

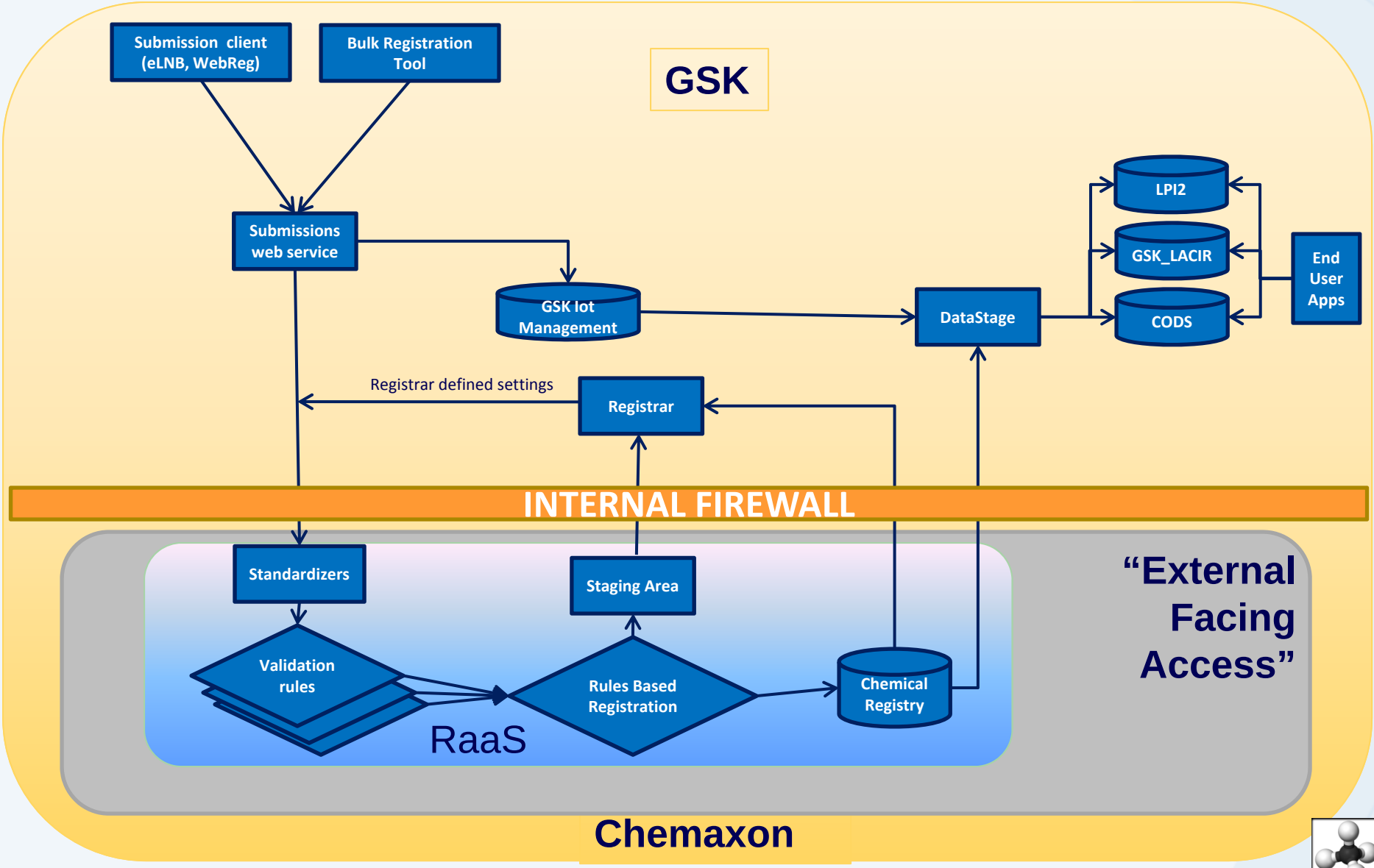
Coming to compromise

- Once the working prototype was in place, the GSK team could see the benefits of working with Chemaxon as a SaaS supplier
  - Members of the team discussed the SaaS approach with ChemAxon
  - The group re-assessed what we were truly trying to get out of a SaaS delivery:
    - Lowered support and maintenance costs
    - Quicker turnaround of releases
    - Single payment structure based on # of compounds registered
  - We also recognized that the liability issues could be avoided if GSK data was protected at GSK Sites using GSK security.

Progress

- As prototype development progressed, the GSK accepted that the Chemaxon approach would be the most sensible solution and most likely to succeed.
- Chemaxon became interested in taking the project on as a new addition to their product line.
- GSK realized that the issue of IP Security and Liability was not going to be easily solved, so the Team engineered a solution that would allow Chemaxon to have control over the hardware and software, yet maintain the application out of a GSK secured data center.
- The new configuration would allow Chemaxon the control they needed to manage the software as a SaaS product, but not expose GSK IP to unacceptable security concerns.

Registration Domain – The Final Architecture



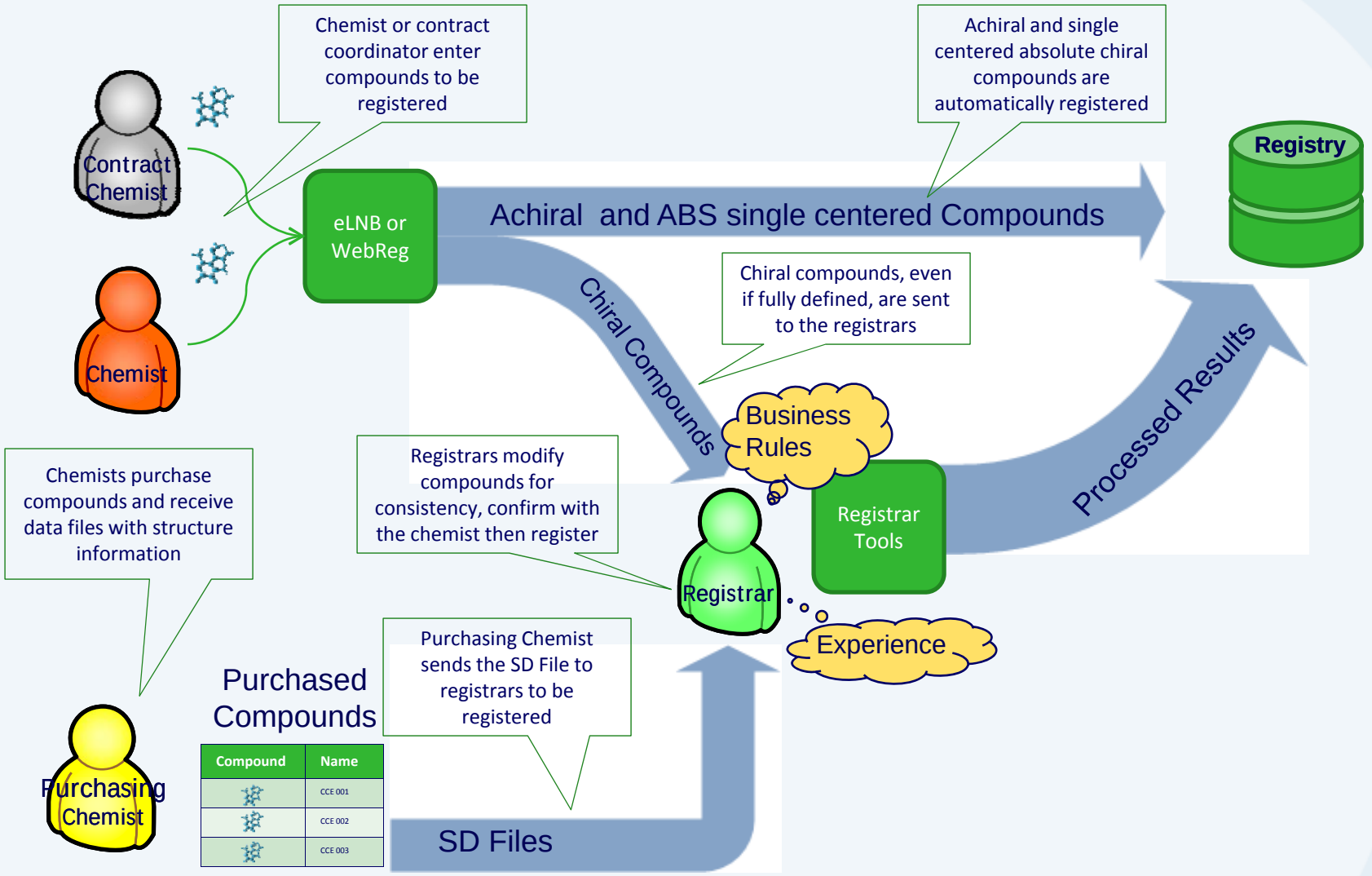
The GSK Implementation

- Once the decision was made to go with Chemaxon, the GSK Team defined the following activities to be completed for a successful transition to the Registry as a Service (RaaS) model:
  - Migration of existing registry data
  - Re-integration of supported systems
  - Changes in Registrar Business Practice
  - Registrar acceptance
  - Changes in End user Business Practices
- In order to understand the magnitude of change required, you need to understand our previous registration system implementation.

Issues with optimizing the current Registry process

- The current registration process has been developed over a 10 year period and is made up of a loosely integrated set of tools and utilities working in concert with the existing Registration system.
  - The system requires registrar to access SD-files on a File share to register
  - The various components are separate applications bolted together to provide the solution. (Cheshire, Registration Client, DB Triggers to create SD-Files, etc.)
- The tool has never been positioned as an 'End User' tool. It has always relied on the knowledge and business understanding of registrars to work efficiently.
- The current system does not allow for easy reconfiguration of automation rules to allow for further automatic registration of compounds
  - There are several different rules engines that need to be configured
- There are multiple points of failure in the overall process and it can be difficult to determine where the process 'Failed'.
- The current system is based on SMILES while all downstream systems expect MOL representation which has caused some difficulties in integration.

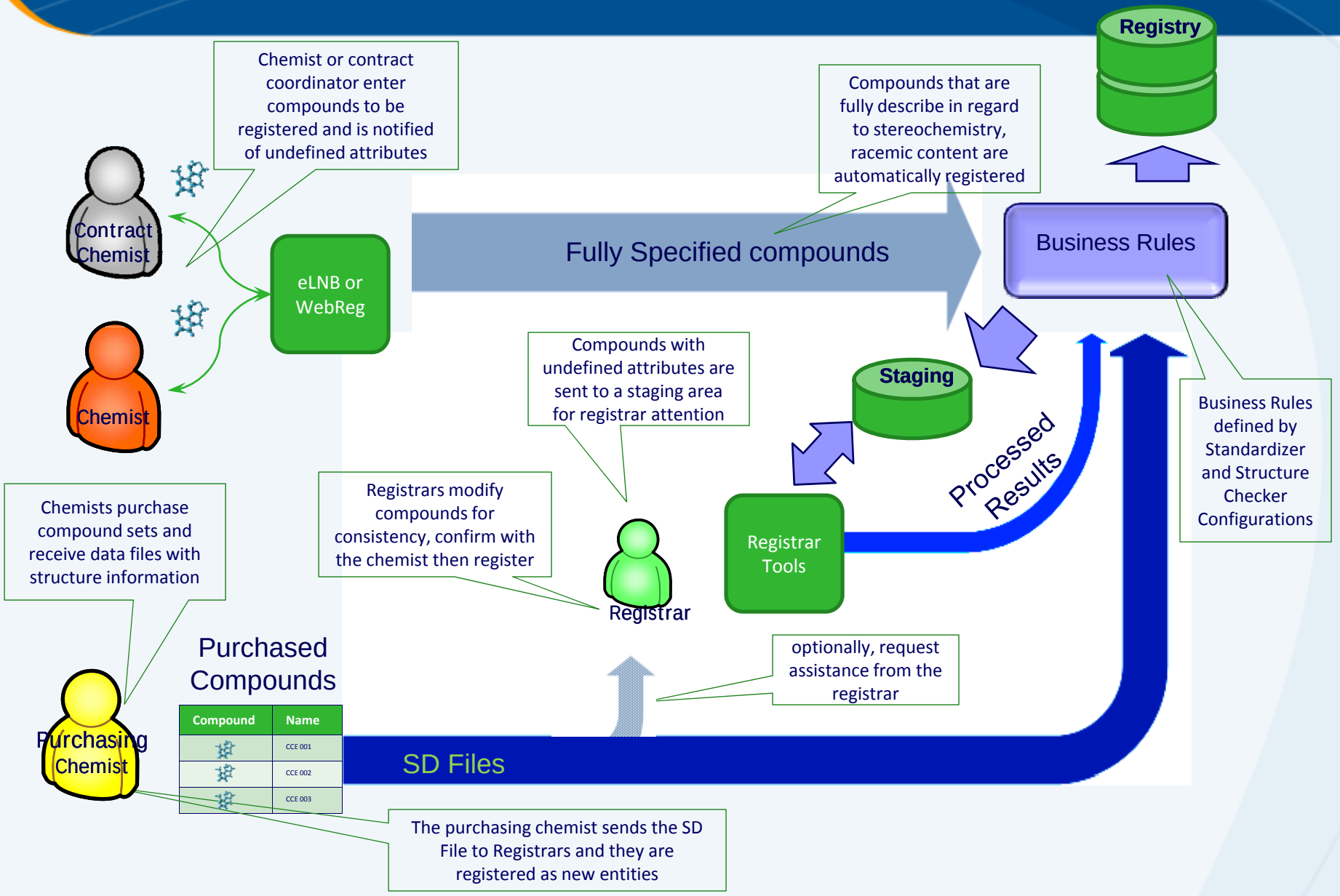
Current Logical Flow of Submissions to Registry



Activities and goals for Phase I

- Replace existing functionality with a more flexible alternative
- Get the application working with all the upstream and downstream components
- Developing confidence in the registrars who will “own” the system
- Tweak the Rules Engine to (at a minimum) produce the same level of automatic registrations
- Allow Purchasing Chemists to bulk load purchased compound sets

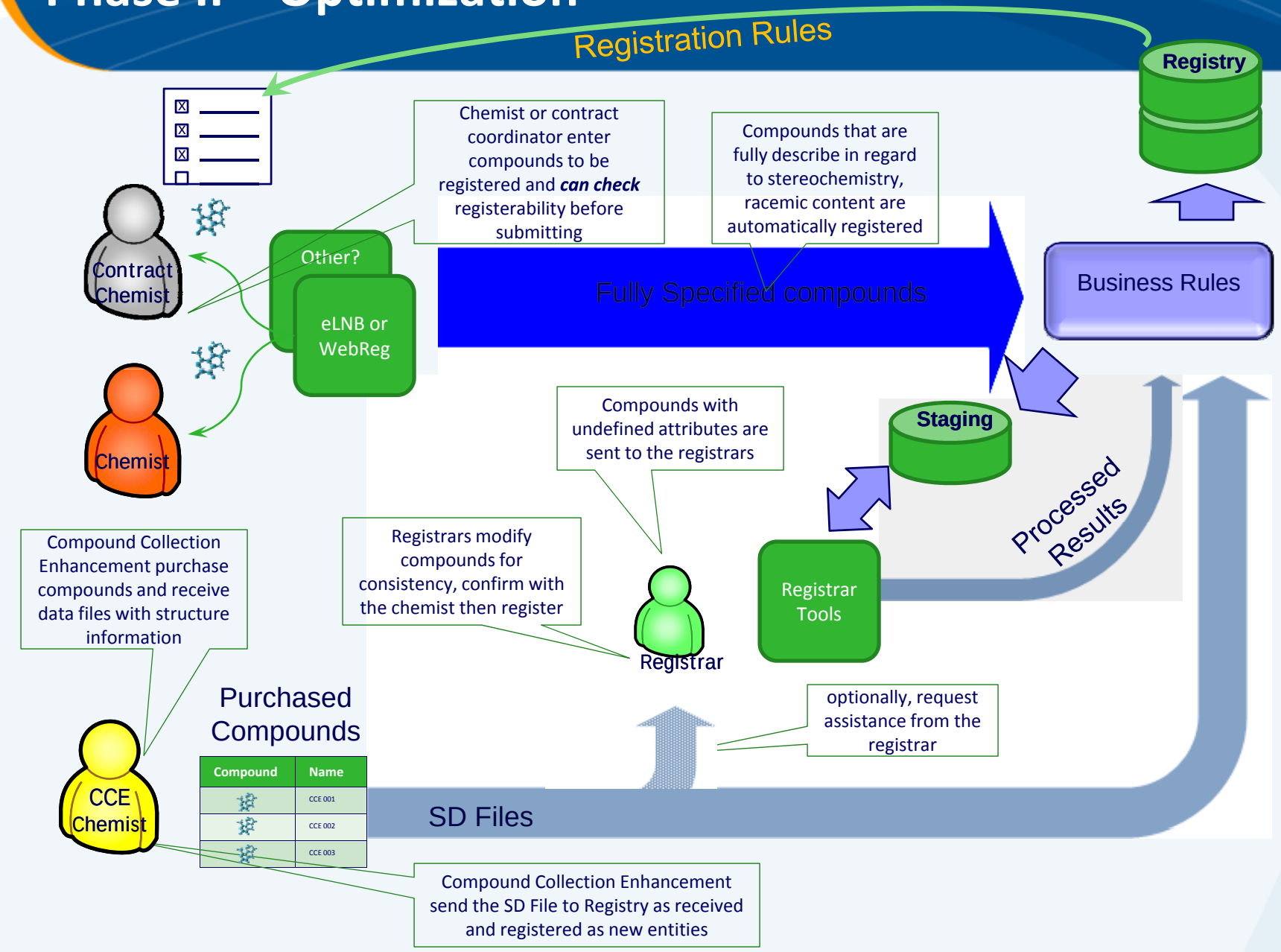
Phase I - Laying the Groundwork



Activities and Goals for Phase II

- Provide Feedback mechanism to chemists to assist in definition of structure to increase automated registration percentages
  - Automated registrations provide almost immediate feedback for further compound testing
  - Samples can be submitted to Compound Management faster
- Improve Registrar tools to aid productivity

Phase II – Optimization



Thank you for your attention!

Questions?