Functional and Economic Justification for Service Robotics in the Pharmaceutical Industry

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ABSTRACT

This paper describes the development of functional and economical justifications of a service robotic system for a large Pharmaceutical Company. The approach followed in the analysis is to identify a plant suitable for improvement in the manufacturing process and then identify areas that could potentially benefit from robotic systems. Furthermore, system development is carried out in phases by addressing goals of increasing difficulty. The objective of the project is the development of a service robot for maintenance and quality control of a production line. However, this goal alone is not sufficient to justify a large technology investment since too few plants would benefit from this innovation. To solve this problem, a phased approach is proposed, which would initially address the development of a logistic robot, and then add measurement and manipulation capabilities to the mobile base. The technology required for the first phase is almost off the shelf and chances of achieving the proposed objectives on time and within budget are very good. This paper summarizes the main technical requirements of this project and the economic anakyis needed to demostrate the validity of the proposed approach from a business perspective.

Keywords Logistics, mobile robots, sterile room, robot economics.

1 INTRODUCTION

The issues addressed in the paper are key to the introduction of service robots to industrial enterprises, since new technologies must be assessed with respect to hard economic and organizational facts. The approach followed in this analysis is to identify a plant suitable for improvement in the manufacturing process and, with the support of plant managers, identify areas that could potentially benefit from robotic systems. Furthermore, system development is carried out in phases by addressing goals of increasing difficulty. In this way, should the Company decide to interrupt the project before its final goal, partial results would still be valuable, self contained, contributions.

The final objective of the project is the development of a service robot for maintenance and quality control of a production line in sterile rooms. The robot should be able to perform environment monitoring, react to changes with simple actions, clean some areas, and perform periodic operations. These actions would improve production quality since human presence is often not desirable in sterile production lines, and should be minimized. A phased approach is proposed for development of this system, which would initially address the development of a logistic robot, and then add measurement and manipulation capabilities to the mobile base. Many plants would benefit from this technology, thus showing a potentially attractive rate of return on the investment. Other benefits from robotic use in production lines would include image recognition, improved market image with respect to other pharmaceutical companies, additional potential applications within the Company, and potential spin off activities.

The technology required for the first phase is almost off the shelf and chances of achieving the proposed objectives on time and within budget are very good. The positive result in this first phase would increase the likelihood of the Company supporting the full development of a service robot. The logistic robot should operate in a partially structured environment, require low environmental engineering, and have a limited set of autonomous capabilities. The robot will be equipped with standard features, such as obstacle avoidance, object and pattern recognition, and path optimisation. At a later time, additional cooperating robots could be added to the system. While these features are almost common knowledge within the research community, we feel that the development of a robotic system with an economic value for a commercial Company would be a truly significant result.

The robot proposed for the second phase would use the same mobile platform, with improved design and materials, and with the addition of simple capabilities such as cleaning, environment monitoring, and autonomous data processing. Robots will be commanded by an interface allowing an operator to supervise the robot with simple functional commands in a semi-natural language. A simulator will permit testing and operator training.

Issues specific to application in a pharmaceutical environment include safety and medical regulation, which are currently not considered by robotic researchers. Most of these issues are still undefined since robotic systems have never been used in similar applications, thus the procedures that we will develop would set the stage for future systems. In particular, if the robot is to perform regulated activities, we must address the issue of software correctness. Critical tasks may include selection and transport of raw material from storage to production, tests in the production line, simple maintenance and repair, and finished products transportation. Each tasks is regulated and robot software must be validated to ensure its correctness. Furthermore, human-robot interaction is still the subject of discussion with respect to safety and levels of interactions.

This paper addresses the preliminary phases of this project, namely the analysis of the state of the art of similar systems, to show the lack of suitable commercial alternatives, the analysis of current logistic functions within a manufacturing plant, to develop suitable functional requirements for the robot, and the economic plan for the development, to give the project a solid financial structure.

2 STATE OF THE ART SUMMARY

The goal of this project is to provide and demonstrate the technologies for transporting safely and efficiently goods in partially structured environments populated by humans and other moving machines. The latter sentence points out also the main limitations of current mobile robot technology. Mobile robots are well suited to perform repetitive motions in well known (structured) and static environment, where the need of sensing the environment and paying attention to unexpected events is minimal. This is not common for service applications, i.e. tasks that normally involve humans, tools, and not well known (unstructured) environments. These tasks are often carried out in crowded environments, such as floor cleaning in train stations and supermarkets, material transport in hospitals, and wheelchair navigation in public places. These environments are also dynamic, i.e. change with the time of the day depending, for example, on the arrival schedule of the trains, or the time of patient visit to the hospital. All these characteristics are present in the application described in this proposal, even though at a lower level of complexity. In fact, the warehouse environment is:

- partially structured, meaning that some of the obstacles have a fixed position and others change place periodically,
- dynamic, since there are moving obstacles represented by forklifts and people,
- it is public, since there are people moving around.

However the warehouse environment can be controlled, by adding sensors and signs, to make the problem of robot navigation less difficult. Thus the proposed system is also very interesting from a scientific point of view, since it represents a meaningful application of robotic technology to a problem, which can be solved in a reasonable time.

Mobile robot navigation has been a very intensive research field during the last decade. However, in spite of substantial results achieved in laboratory experiments, this research has not moved yet into real industrial applications. Several reasons can explain this lack of impact on manufacturing, such as:

- impractical development because of complexity, size or cost of the solution;
- lack of focus on the real needs of the user community (in particular, how the user shares control with the equipment); and, finally,
- lack of test and evaluation in real situations, to demonstrate system effectiveness to prospective users in their true work environment.

There are however, several examples of practical technology development that can be used as guiding examples. Landmark-based navigation, i.e. the approach to robot navigation that does not require extensive environment modifications, is becoming more effective and allows the development of mobile systems that are far more flexible than wire-guided systems. For example, LazerWay (http://www.lazerway.com) has equipped more than 7000 AGVs (in 700 installations) with this technology. Another important observation regards hospital environment, since they are among the most advanced users of intelligent transportation. About 80 hospitals world-wide are now using the Helpmate (http://users.ntplx.net/~helpmate) [20], autonomous transport system (from HelpMate Robotics Inc.) to carry various items (meals, medical records, linens, diagnostic samples). New prototypes of mobile transportation systems are also available for single users. New vehicles are being proposed by the Praxitel project (automated cars, INRIA) and by Robosoft (http://www.robosoft.fr/). The latter is the Cycab, a small vehicle for public individual transport in urban areas. The effective use of mobile robots will also force researchers to solve the problem of managing and controlling a number of robots in the same environment. Projects like MARTHA (ESPRIT 3 for container transport) and Praxitel, have explored these issues. Finally, there have been several demonstration of mobile robot navigation in public, and often, crowded environments, at Museums in Pittsburgh and Bonn, at the Ulm train station and the Hanover fair (MAID wheelchair), and big department stores. The challenge of this project is to tackle the complementary aspects that have not yet been sufficiently addressed and which are necessary to make the complete concept become reality.

From a technology point of view then, the project proposed here will address the two main objectives of:

- fostering a more effective technology transfer between research laboratories and real manufacturing environments, and
- develop a few key technologies essential for an effective use of mobile robots in real environments.

Some of the basic technologies that will be addressed during this project are the following.

1. Mid-range robust navigation in a crowded environment with minimal environment adaptation. This technology addresses the need of enabling mobile robots of moving on medium

length (100's of meters) in the presence of people without the need to add guidance signs and beacons in the environment. Robustness refers to the need of developing navigation algorithms that are robust to errors in sensing and that cannot be confused by varying environment conditions.

2. Human vehicle interaction. The system should be designed to comply with human behaviour and to facilitate human acceptance. It involves several complementary aspects:
   - Interaction with the user, who, in our case, is the person controlling the robot.
   - Interaction with other humans in the environment. The vehicle should be able to detect human motion and to adapt its behaviour accordingly.
3. Fleet management. Eventually robot transportation will integrate several vehicles in the same environment and therefore issues such as:
   - Distribution of tasks among the robots and the control centre,
   - Coordination among vehicles,
   - How to solve conflicts among robots and humans.
   - Cooperation between robots and humans.

These three technologies will ensure robustness to uncertainties, to presence and close interaction with humans, and to differences between the real environment and its "mental" representation by the robot. This project aims at moving one step ahead towards the effective usability of an automatic transportation robots. This will be achieved by meeting the following constraints:

- Real environment (real warehouse facilities, not a laboratory) with large dimensions (several areas, not a single room).
- Installation and testing of transportation system complete in all its aspects - from complementary infrastructure to safety devices - in order to run realistic demonstrations.
- Quantification of the results by measuring human acceptance of the system.

2.1 Past Work in Robotic Transportation

The study of people and goods transportation systems is an important area of research and development in robotics, because of its potential scientific, economic, and social payoff [7]. Technical challenges of this application are unstructured elements of the environment, system reliability and serviceability, and autonomy during unsupervised operation. Among the many possible applications of robotic transportation, logistic systems are among the most promising ones.

One of the most studied areas, and the most relevant for the project proposed here, is research on intelligent wheelchairs, since no reference is available on light logistics robots. Navigational aids for powered wheelchairs, as preliminary research results, appeared in 1980s. The concept of an intelligent wheelchair that can assist the wheelchair driver has existed for over a decade [1]. In the late 1980's the Swedish Permobil company developed a 'track follower' module to enable their wheelchairs to follow taped floor tracks and ultrasonic sensors to detect obstacles [2]. In the past few years, researchers have developed wheelchairs with systems for obstacle detection and avoidance [4], autonomous wall-following and negotiating doorways [11] [5].

In the UK, the CALL Centre has been developing infrared track followers, collision and ultrasonic sensors since 1987 [6], while Challey Heritage Engineering Department in Sussex has developed inductive track-following and ultrasonic obstacle detection systems [3]. The Wheelchair Centre of CALL Centre, aims at the development of the so-called Smart Wheelchair, which helps its rider by taking on some of the driving tasks. The European TIDE Initiative under the Telematics Programme has also supported two projects developing sensor aided systems for power wheelchairs: SENARIO [12] and OMNI [10][13]. The main objective of the SENARIO project is to develop a prototype of a sensor aided intelligent wheelchair navigation system, applied on a commercial powered wheelchair for use in indoor environments [17]. SENARIO achieves fully autonomous navigation in indoor environments with two modes of operation: I) Semi-Autonomous Mode where the system accepts incremental commands from the user, and II) Fully Autonomous in which a command like 'go to goal' is planned and executed autonomously. The OMNI project aimed at the development of an omni-directional mobility aid to powered wheelchairs. The drive of this system is based on Meccanum-wheels. The wheelchair is equipped with ultrasonic and infrared sensors and a manipulator. The project achieved the goal developing a wheelchair that is able to move in any direction and the linear motion to be combined with a rotation around any given point.

A first design concept for a self-navigating wheelchair for disabled people is proposed in [14]. The sensor equipment of the wheelchair included wheel encoders, a scanning ultrasonic rangefinder and a digital camera. The system is able to navigate fully autonomously in a simple office. In [15], the system NavChair is described. NavChair's important functions are automatic obstacle avoidance, wall following, and passing doorways. A hybrid vehicle RHOMBUS for bedridden persons is described in [8]. RHOMBUS is a powered wheelchair with an omni-directional drive, which can be automatically reconfigured such that it becomes part of a flat stationary bed. In [9] a hybrid wheelchair equipped with two legs in addition to the four regular wheels is proposed. These legs should enable the robotc wheelchair to climb over steps and move through rough terrain.

3 FUNCTIONAL REQUIREMENTS

3.1 The warehouse and its operation

The facility chosen for the development of robotic technologies for the pharmaceutical industry is the Parma plant; in particular we plan to set up a robotic package transport system in its warehouse. This warehouse is distributed over two separate buildings, a primary (P) one, and a secondary (Q) one. Warehouse P is equipped with two vertical storage systems, 12 stories each, and borders the Quality Control (QC) area. Vertical storage systems are automatic drawers, holding small parcels and moving on operator's request. The first installation of the robotic transport will be in this warehouse. The second warehouse, Q, with three vertical storage, 6 stories each, will be upgraded to robotic transport at a later time if required.

In order to identify the best robotic equipment for this application, it is necessary to examine in some detail the operation of the warehouse P. With respect to receiving procedures; goods and materials are moved around on pallets. The flow of goods and materials in the warehouse follows these main steps.

- Receiving, acceptance and storage. The initial delivery is on pallets where they undergo the acceptance verification of the shipping documents. Then, the operator inserts goods data in the information system and labels the shipment, thus acknowledging its nature and its recording. The delivery is then taken to different locations in the warehouse, shelves, vertical storage, or controlled rooms.
- Quality control operations. QC check is carried out on new lots by taking a test parcel received with the rest of the shipment and marked for quality control, to the QC office. The test parcel is taken directly to the area in front of QC, from where it is picked up by an operator of that department together with other parcels waiting for testing. Parcels already tested are also in front of QC and are taken back to storage. Samples of materials shipped without test parcel are also brought to QC. Twice a day, samples are also taken from warehouse Q to QC with a shuttle, either a truck or a forklift.
- Transport to production lines. Materials requested by the production lines are taken from the warehouse to the requesting department and identified by a number, marked on the material and on the department door. Requested materials are moved by forklift, and left in front of the department door. Left over materials, to be returned to storage, are also found in front of the department door, and taken, either by forklift or manually, to the proper storage in the warehouse.
- Vertical storage operations. Small parcels are assigned to storage drawers, depending on parcel size and on the emptiness of the drawer. Before storage, the drawer's bar code is compared to the parcel's one by using a hand-held device. Data on parcel storage are sent to the local information system, for real time inventory update. An operator who issues a request for the holding drawer to the vertical storage system via a touch screen retrieves parcel.

3.2 Robotic Handling of Warehouse Goods

Several possible applications have been identified for use of robotic systems in the Parma warehouse. However, in this context, the most suitable application is the transportation of small parcels. Larger parcels in fact, require large robots, such as AGV (Autonomous Guided Vehicles) type machines, which will be hard to adapt to the existing warehouse environments and will not provide any technology leverage for other manufacturing applications. Instead, this project aims at developing the groundbreaking technology for the introduction of robots in the pharmaceutical industry, and thus we need to develop a small robotic platform amenable to various adaptations to the manufacturing process.

Parcel transfer will be limited to parcels of various forms, but whose maximum dimensions are less than 40 cm X 40 cm X 60 cm, and whose weight is less than 20 Kg. This information is not stored in the local Information System and therefore small parcels must be identified and classified by size, weight and form by using the information about their content. The main materials/goods that are shipped in small parcels are:

Instruction sheets. They are mostly (up to 90%) shipped in pallets.

Returned materials. They are carried from the production areas to the warehouse.

Labels. Parma receives about 5000 lots, 70% of which in small parcels.

It must also be noted that these figures are expected to double because of expected manufacturing network rationalisation in the next years.

Small parcels are moved in the Company during different delivery types:

- Delivery to/from controlled areas.
- Deliveries to/from Quality Control.
- Deliveries to/from production.
- Deliveries to/from vertical storage system.

In all these cases, small parcels are involved, but not all delivery types are ready for the immediate insertion of robotic technology. Traffic between storage and controlled areas is declining, because of the decreasing number of goods (for example labels) that require a controlled environment. Traffic between storage and QC would not justify a robotic system, since routes are very short. However, this traffic could also be considered as probably of interest for other sites, and there is no wasted time for a human operator handling the transport. The application of robotic transport in the Parma warehouse that is the closest to an economic justification is the access to the vertical storage system, because of the execution time involved, and because the operation is already partly computerised and planned for further enhancements by interfacing it with a new Information System. However, economic justification alone should not be the only driver of this project, since technology development and education should also have a prominent role in justifying this project.

4 THE WAREHOUSE ROBOT

The approach that we propose is to purchase a commercial mobile robot and to equip it with suitable sensors and navigation algorithms to make it capable of navigating the existing environment represented by the Parma warehouses. The constraint will be to minimise the environmental engineering, i.e. the project will not require extensive modifications to the existing warehouse and the addition of a complex guidance system. The complete system will consist of a single mobile robot specialised to handle small parcels of the dimensions specified above, the operator control station and a few environment sensors, such as wall markers (bar codes, laser reflectors, etc) that would help localise the robot. This system could be expanded, at a later time, by adding additional mobile robots that can exchange information and cooperate to carry out more complex tasks. Significant features of the warehouse robot will be:

- Obstacle avoidance, to move safely in the warehouse,
- Object and pattern recognition, to identify specified packages and locate them in the right shelves, and
- Path optimisation, to minimise time and distance during goods transportation.

While carrying out these operations, the robot could also memorise interesting data about stored goods, monitor warehouse throughput, and perform material flow and inventory processing with a future interface to the new SAP information system.

The warehouse robot will be commanded by an interface. This interface will allow an operator to give simple functional commands to the robot, specifying type and quantities of goods to be moved. Commands will be given once to the robot, which will then carry out the task automatically every time is required. The interface will convert task commands given in simple language into specific robot commands. The interface will also allow monitoring of robot position via a camera installed on the robot. A simulator will permit to test the robot actions and will be used for training operators on robot capabilities and commands.

Navigation and localisation algorithms for the mobile robot will take advantage of the known configuration of the Parma warehouse, where obstacles occupy mostly fixed positions and there is little human traffic. However, to account for mobile obstacles, such as workers and forklifts, navigation algorithms will take advantage of previous work for the autonomous navigation of intelligent wheelchairs. These algorithms, coupled with the sensor suite of the robot, allow the avoidance of all fixed and mobile obstacles, thus ensuring motion safety, while minimising travel time.

The introduction of mobile robots in the warehouse environment is a necessary evolution of goods handling procedures, which can result in a significant benefit, precursor to a more intensive use of robotic technology in the pharmaceutical industry.

The main project phases are:

- Test the concept in a non production environment, i.e. the laboratory of robotic of University of Verona.
- Perform the industrialisation in the Parma warehouse mentioned above.
- Roll out the technology in other interested sites.

5 FINANCIAL JUSTIFICATION

Robotic technology is expected to handle most of small parcel movements in the Parma GSK warehouse. During 2001, there have been approximately 10,000 shipments of labels, equivalent to the same number of small parcels moved to storage. The average time to store a small parcel in the vertical storage by a human operator is 9 minutes per box. From these data, it follows that about a Full Time Equivalent (FTe) could be saved by using a robotic transfer system for the vertical storage warehouse. Considering the expected increase in number of small parcels, the time saved will be closer to two FTe, especially when considering that there are dead times during a work day.

The financial analysis of the project included the expenditure for Proof of Concept Euros in the period 2002-2003 at laboratory of Robotics of University of Verona, the cost for Industrialisation Euros in the period 2003-2005, at Parma Site, and the expenditure for the roll out in 5 GSK sites in the period 2005-2007.

The benefits have been estimated on the base of business case created for Parma site. At Parma 2 FTe should be saved after completion of industrialisation. After roll out of robotic system to all sites savings for 12 FTe are expected. Savings will start in 2005 with 3 FTe and will finish in 2009 with 12 FTe.

Critical issues associated with this proposal are:

- Use of robot in a manufacturing environment can cause a resistance by workforce and matter should be discussed with HR department.
- Competitive advantage in carrying out dangerous operations, working in not comfortable environment or critical area can be matter of sensitivity.

6 REGULATORY COMPLIANCE

To successfully introduce robotic systems in a conventional pharmaceutical plant, as opposed to a car industry environment, we need to address several compliance issues. Most of these issues are still undefined since robotic systems have never been used in similar applications. Furthermore, human-robot interaction is still the subject of discussion and material properties, it is reasonable to assume that robots must follow the same guidelines of all sterile room equipment. However, if the robot is to perform some critical activity, we must also address the issue of software validation. Critical activities may include selection and transport of raw material from storage to production, tests within the sterile room, simple maintenance and repair, and finished product transportation. Each one of these phases is regulated and robot software must be validated to ensure that it will perform correctly. To address this issue we will utilise the same procedures used in other high risk activities, such as robotic surgery and space exploration and in compliance with software standards for the pharmaceutical industry CFR21 part 11. Finally, we will equip the robot with VDE approved safety systems for human environment, such as supermarkets and railway stations, to ensure collision avoidance with humans in all operating conditions.

6.1 Health, Safety and Environmental

Communication with the robot will occur via radio frequency (RF) link implementing Ethernet communication protocol. We will use transmitters approved for human use, and ensure that transmitter strength is compatible with other warehouse and sterile room equipment. Laser sensor will be conforming to European safety regulations for use in environments populate by humans.

7 CONCLUSIONS

This paper has presented a brief summary of the preliminary considerations that form the basis for the research and development of a light weigth logistc robot for a pharmaceutical manufacturing plant. This project is a first step of a phased project that would, if successful, lead to the development of fully robotized drug manufacturing plants, that would increase quality and quantity of medication production.

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