APPENDIX 1

Biogenetica
San Jose ITSA Replacement

Business Case

Business Sponsor: **Brian Smith**
Project Manager: **Ram Kumar**
Project Cost Centre: **00417**

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1. Management Summary

Background:	This is a replacement project for an existing ITSA system that is no longer supported and is not Millennium compliant.
Recommendation:	To evaluate two short listed suppliers and select the best solution. Implement during 1998. An ITSA replacement system will provide ongoing net benefit to BioGenetica.
Scope of Project:	The replacement of the ITSA system in San Jose R&D. This includes process enhancements, but the aim is to deliver existing functionality.
Project Sponsor:	Brian Smith
Project Cost:	Circa 600 K Detailed project costs are the output of Phase 2 of the project.
Tangible Benefits:	The primary benefit is an ongoing headcount saving, the equivalent of 240 K. More details are shown within the document
Intangible Benefits:	The ITSA is a fundamental part of, and supports, the Biotech Industry Alliance (BIA) Accreditation. Improved ease of use, particularly for temporary/replacement staff. Modern end-user environment (Windows 95/NT) Improved Management control and reporting
Payback Period:	$3^1/_3$ yrs
IRR:	23 %
Start/End Dates:	Phase 1 – started. End Dec 1997. Phase 2 - start Jan 1998. End Oct 1998.
Risks:	The main risk is the complexity of the equipment interfaces and the automatic update of analysis measurements into the ITSA system. The industry uniqueness of processing machines also poses a challenge, but should be manageable given that this is a replacement application. The consequences of a delay in implementation, whilst these issues are addressed, is primarily a cost issue, although the current application may suffer Millennium problems in 1999. Therefore I would suggest that the replacement work starts as soon as possible.

2. Introduction

An Information Technology System Architecture (ITSA) is a computer network installed within a laboratory or group of laboratories to log samples, gather data automatically from analytical instruments, perform mathematical calculations, track sample progress, produce data reports for customers and provide a database of raw data for archival retrieval.

This document's purpose is to summarise the business case for a replacement ITSA for San Jose Biogenetica's Research and Development. It should be read in conjunction with the Business Requirements document.

3. Project Definition

3.1. Project Background

The current ITSA operating in the laboratories of the four sections of the Emerging Technologies Department (ETD) of R&D was installed some eight years ago, is a highly customised system that is no longer supported by its' supplier and is beginning to suffer breakdowns in both software and hardware. In the last three years budgetary requests for upgrade or replacement of the system have been denied or subsequently cut from the budget. It has now been identified that major elements of both the application software and hardware within the system and its network are not Millennium compliant. The system will, therefore, need to be upgraded or replaced as part of the Millennium exercise.

This opportunity will also be taken to improve deficiencies in the existing systems functionality which currently require a significant amount of management time on resolving operational issues. Additionally the management reporting available within the application is insufficient to monitor day-to-day operations.

Brian Smith has identified the need to replace this system and is the sponsor for its replacement.

3.2. Statement of Business Need / Requirements

A separate document 'Business Requirements' details the Business Requirements in more detail. They are largely based on current working practices although new functionality available in the latest releases of ITSA software will be utilised where it is appropriate to do so.

The original business justification for the ITSA included improvements in the efficiency and productivity of the various sections of ETD without increasing staff resources. It was also to improve the quality of the data produced by removing operator involvement in data collection and transcription. At that time it was envisaged that extra staff (minimum 3 people) would be required if the ITSA was not purchased.

Since the introduction of the ITSA we have seen improved efficiency, productivity and data quality. An example of this is that the number of tests per year identified in the original justification was 120,000 against an estimated 160,000 this year, **a 33% increase**. This increase has been achieved without extra staff and against a decrease in staff numbers in some areas, e.g. QC, have been reduced 5 to 3 people. It can be argued that the change in staff numbers (non take up of 3 people against ITSA installation and subsequent 2 loss) have provided a year on year saving of approximately $200,000 with increased productivity.

Three of the sections within ETD now have Biotech Industry Alliance (BIA) accreditation that is an essential requirement in acceptance of our data by regulatory bodies. The ITSA is an integral part of the operation, audit trailing and data validation of the accreditation.

If the current ITSA is not replaced and subsequently fails:

1. We would not be able to meet the current workload placed on the ETD sections.

2. We would not be able to provide the San Jose plant and other R&D facilities with timely data to fulfil their regulatory obligations.

3. We would not be able to provide the current support level to the various Divisions of R&D and thus to other departments such as Marketing.

4. We would have to revert to manual operations with the subsequent loss in productivity and the possible introduction of data transcription and manipulation errors.

5. To counteract 1, 2, 3 and 4 we would have to increase staff resources. It is difficult to estimate how many this would entail but based on the figures above could represent a yearly cost in excess of $200,000.

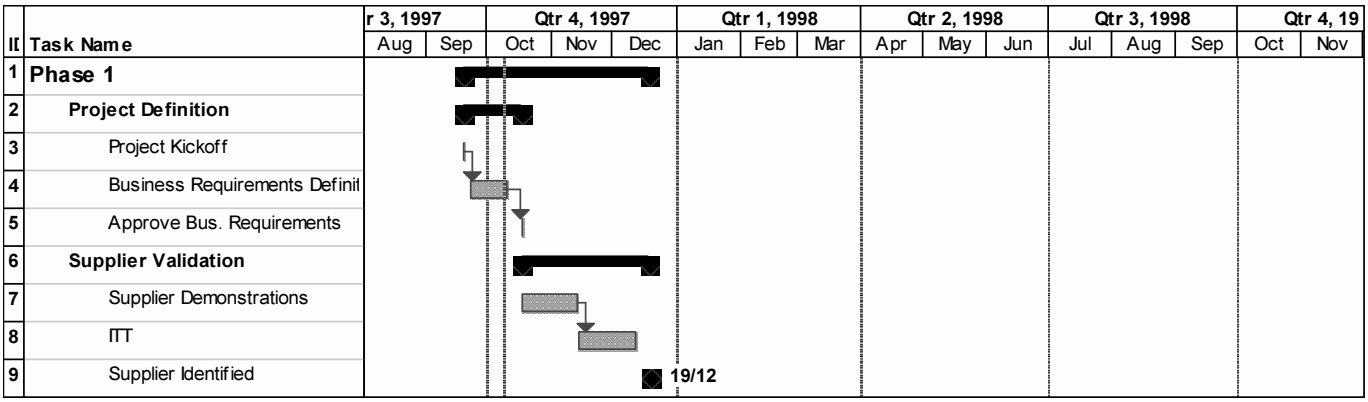
6. We would place our BIA accreditation in jeopardy and all our procedures and audit mechanisms would need to be re-written.

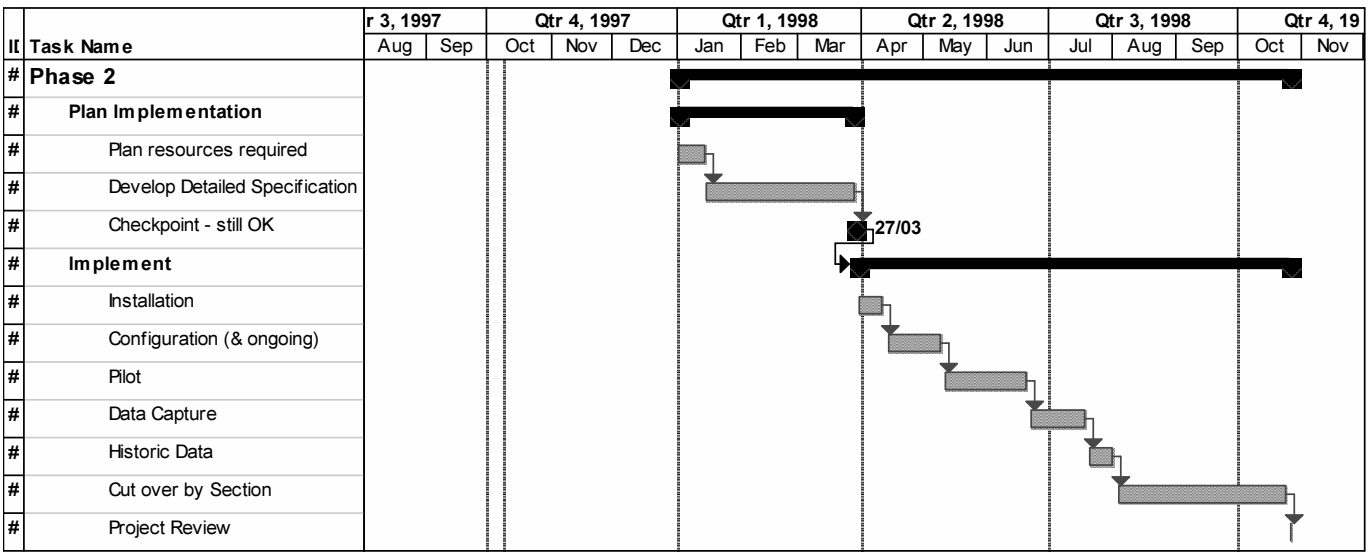
3.3. Objectives

The objective of this project is to implement a new/replacement ITSA system in San Jose by the end of 1998 which addresses the deficiencies of the current system. Disruption to the normal working practices in the labs needs to be minimised.

3.4. Project Scope and Timescales

The project Timescale is shown below:





The scope of this project is to select and replace the ITSA system in San Jose R&D. The first phase requires the selection of the supplier. Phase II will plan the actual implementation of the chosen ITSA and produce an agreed detailed functional specification (and costs), prior to configuring the product to meet exact requirements. This detailed functional specification will ensure that all requirements are met and identify areas which may need further work (e.g. customisation, which should be minimised). The checkpoint at the end of March provides the final decision point (functionality, benefits, costs, gaps).

In the unlikely event that the detailed functional specification shows that chosen solution is substantially deficient the selection of the solution would have to be revisited. Clearly the project sponsor would flag this to Operations IT for action and resolution.

4. Project Details

4.1. Project Costs (including 1st year support)

Project costs will be determined within the first phase of the project in conjunction with suppliers. A more detailed cost will be determined during the planning phase when the detailed functional specification has been written.

Phase 1 costs, excluding user time, involving Vincent Richards and Ram Kumar are 8K.
Phase 2 costs, met from a specific R&D budget, are estimated at 600K based on information obtained from other R&D ITSA implementations (e.g. a subsidiary like La Carte) and are comparable with the estimate below.

The main cost in the project will be the development and testing time for all the equipment interfaces to enable automatic update of the ITSA database with the results of analysis measurements. This costing allows for a detailed spec to be produced prior to implementation. If the Interface implementation proved to be easier than expected this cost might be halved, saving 80K

Phase 1 costs:	8K	
Phase 2 costs -		
Software Application costs:	150 K	30 users max
Software Customisation:	80 K	1 FTE
Hardware platform	20 K	Assume NT solution on Compaq
Interface software	20 K	
Interface implementation	160 K	2 FTE
Training of users	10 K	
New PCs / Mini Terminals	90 K	50 various items, inc printers
Project Management	70 K	1/2 FTE
Total Costs	**593 K**	USD

4.2. Tangible Benefits

These can be summarised as:

- Avoidance of additional headcount as indicated above (at least 5 people).
- Increased productivity (+ 33%) compared to no ITSA system, without an increase in headcount.
- Opportunities for a further productivity (at least 10%) to increase sample throughput with the existing headcount, e.g. by faster system response times and additional automation of equipment interfaces.
- Reduced management time on operational activities (repairing obsolete hardware, resolving system problems)

4.3. Financial Evaluation

The ongoing annual benefit from a ITSA system is a headcount reduction of at least 5 people. This equates to 200 K. Combined with the increased productivity (+33%) benefit which would add at least one additional full time resource, the total headcount cost saving is around 240 K per year.

Ongoing support cost (estimated at 15% of project h/w and s/w cost + 20% of IT resource) is 60K. This includes the partial time of existing IT resources, hardware and software maintenance. (The major project cost is not the hardware or packaged software solution)

The financial consequences of this project are shown below:

	1998	1999	2000	2001	2002	2003	2004	2005
Spend	-600	-60	-60	-60	-60	-60	-60	-60
Benefit		240	240	240	240	240	240	240
Net Benefit	-600	180	180	180	180	180	180	180

NPV = **198** at 12% Discount Rate
IRR = **23%**
Payback = **3.3** yrs

The assumptions above are conservative i.e. taking the life of the ITSA at only 7 years. The previous ITSA lasted nearly 10 years. Increased productivity benefits have been omitted and the savings are restricted to the benefits already being delivered by the existing ITSA system, which will be improved on. Intangible benefits are, by definition, also ignored.

The above scenario ignores any cost of Millennium fixes. Although the current system could be fixed for Y2K problems the other deficiencies such as obsolete hardware, no support, etc, would not. Therefore this is not a realistic alternative as the ITSA system would need to be replaced in the next few years anyway.

4.4. Intangible Benefits

These are:

- The ITSA is a fundamental part of, and supports, the BIA Accreditation.
- Improved ease of use, particularly for temporary/replacement staff.
- Modern end-user environment (Windows 95/NT)
- Improved Management control and reporting

4.5. Risk Analysis

The complexity of the existing system poses a challenge in migrating the current functionality and equipment connectivity to a new system. This needs to be carefully planned with equipment potentially being connected in parallel to both the old and the new system.

The timescales outlined above are tight but achievable. The risk in this area can only be minimised by producing a detailed functional specification prior to implementation.

Sufficient user time needs to be devoted to the project to ensure that functionality is thoroughly tested prior to going live. This necessarily impacts the ongoing throughput and service levels in the lab particularly during the implementation phase.

The non-millennium compatibility of the existing ITSA and the belief that the date '99' has been used as a default in the system implies that the migration must be complete by the end of 1998. The ability of the system to function in 1999 should be tested as part of this project.

4.6. Sensitivity Analysis

As the benefit baseline is conservative the main risk is associated with an increase in project costs.
The analysis below shows that if the project cost increased by 20% the project would still have a positive NPV. Again this scenario ignores Millennium issues, incremental Productivity gains, etc.

	1998	1999	2000	2001	2002	2003	2004	2005
Spend	-720	-60	-60	-60	-60	-60	-60	-60
Benefit		240	240	240	240	240	240	240
Net Benefit	-720	180	180	180	180	180	180	180

NPV = **91** at 12% Discount Rate
IRR = **16%**
Payback = **4.0** yrs

4.7. Implementation Implications / Issues

The availability of laboratory staff is essential to ensure a full definition of requirements and a smooth implementation. One of the project sponsor's roles is to ensure that this expert user resource is available for testing, training, etc. There may be some opportunity to use temporary laboratory staff to free up full time staff.

Although Phase I involves nearly all internal resources it is envisaged that phase 2 will be staffed with contractors, either from the eventual software supplier or another third party. The project management role is key and although this role may be filled by internal resource, the use of an external resource is more likely.

4.8. Organisational Structure

The organisation of the R&D department is not affected by this project.