

## **What is the best approach to using UOVRST™?**

If you are new to UOVRST™, there are a number of approaches that can be used separately, or in combination:

### **Existing Products (somewhere in their life cycle)**

Although it would be ideal to have all existing SOP's and Work Instructions supported by the UOVRST™ format, it is not cost effective due to the large number of documents involved. In most cases, a risk assessment process is used to determine specific SOPs that have the highest cost savings potential. This approach is based on historical quality data, as well as the potential cost of failure. Specific SOPs that deal with activities common to a number of processes or products are also good candidates. Equipment cleaning and general sanitation procedures that have the potential to seriously impact quality as a consequence of product contamination are excellent choices as well. Work that is carried out, most often, by temporary work forces is also best supported by UOVRST™ as there may also be language and comprehension issues that can result in serious deviations. Minimizing the time for setups, change over, routine maintenance, and the trouble-shooting of complex production systems, to keep them up and running, is one of the most used applications of the UOVRST™ process. When production systems are not running they are not making product for sale.

### **New Products (at the beginning of their life cycle)**

This is an ideal application of UOVRST™. By capturing procedures used to generate batches used to substantiate the proof of process (validation batches), the “gold standard” visual reference is established and preserved. This prevents “procedural drift”, defined as cumulative incremental changes to a process, from occurring over the life cycle of a product. The UOVRST™ Library is then used in the training and qualification of the operators that will produce the launch batches. In this way, the development of UOVRST™ is often associated with the validation costs. In many cases a new product will return hundreds of millions and often billions of dollars to the company during its life cycle. Ensuring that the production process remains the same over its life cycle is essential.

### **Rarely used, but important SOPs**

There are occasions, in the laboratory and on the production floor, where an important procedure is carried out periodically but it is essential that it be done correctly. UOVRST™ treatment of these SOPs ensures that the understanding will not be lost even when it has not been done for months or years. Operators can re-qualify on these procedures very rapidly and from any location by taking advantage of a previously established rich knowledge base in UOVRST™.

## **How does using UOVRST™ benefit a site transfer?**

Some companies may launch from one site and then transfer the production to another site later in the life cycle of the product. In this case, a UOVRST™ Library offers the highest assurance that the intellectual capital associated with production of the product will be transferred intact.

### **What is “procedural drift” and how does UOVRSTM prevent it?**

“Procedural Drift” is defined as the change in understanding and execution of an unchanging written SOP that occurs over time. It occurs as a result of inconsistencies delivered to production operators at the time of in-plant training, and is due in part to different trainers offering slightly differing versions of how things should be done. Even though the written procedure stays the same, the procedure is more than likely to be performed according to the instruction given by the in-plant trainer’s “version”.

### **What are some ways in which UOVRSTM can provide a good ROI?**

#### **Eliminating the need to hire technical trainers**

There are a number of situations where a company will create either a temporary or increased permanent training resource to handle specific business situations. Costs associated with this include developing a “train the trainer” course and developing specific training materials to support this instructional approach. UOVRSTM has the content and delivery built right into the process. It provides 24/7, multi-location access to the training material and the intellectual capital is totally retained by the company. Also, temporary trainers may seek employment with other companies and being familiar with the details of your processes the company may lose valuable competitive advantages. A trainer with salary and benefits can easily be a \$100,000 investment per year. UOVRSTM is a one-time cost and will have an excellent ROI if one or more trainers need not be hired.

#### **Eliminating the costs of non-conformance**

Each time a batch is rejected due to employee misunderstanding, it must be rescheduled and manufactured again. Costs associated with this include investigational costs, raw material costs, laboratory testing costs, waste disposal costs, wasted overhead costs as well as financial penalties associated with missing customer delivery deadlines. In cases where a product, that has not met specifications, has been released for sale, non-conformance costs would also include the costs involved in recalling that product. Non-conformance costs at a site can easily be multi-million dollar financial drains on the bottom line.

#### **Keeping a complex production line up and running at its capacity**

On many occasions a complex production line, containing many sub-stations, may drift out of the acceptable control limits and the system will shut down. The business issue is how fast can the system be returned to operation. The Aries Troubleshooting Module consists of software sub-set that behaves in an interactive mode. An additional sub-menu added to the root learning menu allows the user to easily navigate through a cascading logic tree to quickly reach the right fix to get the system up and running as quickly as possible. Each action step to fix the problem is an approved UOVRSTM clip. Fully competent employees set up, maintain, and troubleshoot complex equipment faster than employees who exist in some partial state of unconscious incompetence. This results in higher capacity for the equipment.

### **How do you treat the various activities within a SOP?**

Generally, there is a gradation of complexity within every SOP. In order to ensure complete visualization and learning integrity within an SOP, every action step is visualized according to the degree of attention required. Each action step is graded in a four-step assessment of complexity. Simple steps are briefly mentioned in order of occurrence, whereas as the complexity of the activity or action step increases, more time is spent on the activity.

### **What is the difference between using UOVRST<sup>TM</sup> and digital slides/PowerPoint with a lecturer to train operators?**

There is a significant difference in the learning potential between the two methods. A single digital photograph does not transfer any of the *time based motion activity*. UOVRST<sup>TM</sup> captures “*reality*” and clearly shows how the activity is performed as a function of time. The single digital photograph can only show *what* we are talking about but not *how* to do it. With UOVRST<sup>TM</sup>, the brain is supplied directly with visual continuity from all of the action steps and associated visual modifiers. The learning process is much less effective with simple photographs. The scripted and professionally narrated UOVRST<sup>TM</sup> clip is reproduced exactly every time the presentation is viewed. With a lecturer using PowerPoint slides, the accompanying narration varies with every presentation. The lecturer must also have a high knowledge base, whereas with UOVRST<sup>TM</sup>, that knowledge is contained within the media presentation. A lecture type presentation does not facilitate the learner’s ability to review portions of the learning if they “*wink-out*” during the lecture. With UOVRST<sup>TM</sup>, the learner can review the presentation on an individual basis, 24/7, at any location, until they are confident with the material, without being self-conscious in front of others. UOVRST<sup>TM</sup> also allows the library clip to be viewed at the location using portable iPod technology. UOVRST<sup>TM</sup> provides learning potential and flexibility not available by any method. UOVRST<sup>TM</sup> is the most effective technique to capture the intellectual capital associated with your processes in a self-contained module with the highest transfer potential of knowledge.

### **We have video cameras in-house....why can’t we do this ourselves?**

The best-in-class companies know that a total focus on their core competencies is necessary to achieve a leadership position in the market place. They are quick to separate what they *could* do from what they *should* do. The production aspects of each library clip are state-of-the art, using the latest professional cameras, editing and effects resources, narration, and special effects from award winning creative and technical specialists. The difference between a highly effective commercial and a poor infomercial is the ability to time-compress the selling argument. In this case, less video is more learning. The Aries Communications Group Inc. created the UOVRST<sup>TM</sup> and has built a best-in-class organization that innovatively combines the necessary scientific and engineering skills, with the creative media skills, to produce process-based learning that maximizes understanding.

### **How much of our resources are required to get this going and to keep it going?**

Existing computer hardware can be used, and both QuickTime™ and Flash software can be acquired on any computer, without cost. Aries staff will work with your existing staff to discuss issues regarding specific SOPs and Work Instructions and also to arrange schedules pertaining to principal cinematography. All that is required from your company is a small office space while Aries staff is on-site and also a secure space for camera, related equipment and supplies.

### **How portable is UOVRST™?**

UOVRST™ is the most portable learning tool on the market today. It is delivered to you in the latest QuickTime™ and Flash compressed formats, at broadcast resolution. We can also format for use on the video iPod (320 x 240), or in web streaming format. The media and Aries designed Flash interface are provided on a USB Flash drive (to be retained by the client). Employees have the option of reviewing the library clips on a company-designated workstation, using our iSUD™ hierarchically structured visual database with its integrated cross platform media player, or they can view the clips at any location on an iPod. Since most pharmaceutical production environments are job specific, operators can complete performance qualification assignments by reviewing job specific UOVRST™ Library clips that are pre-loaded onto iPods and reviewed at any time and from any location. For larger group discussions between shifts, orientation sessions and for team meetings, a local LCD monitor linked to an iPod docking station makes sharing job specific information ideal. The portability of UOVRST™ also provides your company with an excellent way to transfer intellectual capital between sites when required.

### **What is the cost structure for UOVRST™?**

Costing is based on standard packages that include a free on-site UOVRST™ business assessment, a separate pre-production on-site visit, a pre-production session at the Aries studios, a principal photography visit on-site and a post-production session at the Aries studios. Cost is calculated based on the rate for the least amount of finished media and that rate decreases as the amount of finished media increases. Normally, and for scheduling purposes, projects are not scheduled for more than three hours of finished media.

### **How are employees involved in the creation of the UOVRST™ Library?**

The purpose of the UOVRST™ Library is to capture the intellectual capital, that is, the best understanding of the *how* and *why* of critical company production processes. Much of that intellectual capital exists as knowledge only in the minds of employees. The goal of the UOVRST™ Library is to capture all of the knowledge, wherever it exists, and present the optimum explanation. Aries will capture and summarize the best understanding of the critical aspects of each unit operation of a process and like a great

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movie, each UOVRST™ clip needs to start with a great script. To that end, the company needs to make available those individuals who have the best understanding of the issues, knowledge, and experience associated with a given process. This may involve a scheduled interview in an office, or an interactive session at the process site. Many companies also realize that this is an opportunity for them to bring a number of employees together to discuss the process in question to develop the best understanding based on the principle “*that all of us are smarter than any of us*”. That process alone, signals to the employees that the company is committed to driving out non-conformance costs and positions the new learning tools as something to be taken seriously.

At first, it may seem like this approach is consuming a lot of resources, however it’s important that employees aren’t just busy “*doing things right*”. They must be busy “*doing the right things right*”. Driving out cost is one of the “*right things*” to do in any company. To capture the best explanation about how to execute the activities within a given process, it is necessary for companies to reprioritize employee daily activity so that they can provide input that will result in a UOVRST™ library containing fully leveraged intellectual capital maximizing employee understanding within the company.

The goal is to ensure that all processes will be done “*right the first time, every time, in the shortest time*”. This is the condition that drives out non-conformance costs and maximizes productivity.

### **Why is Visual Learning the method of choice?**

For most of mankind’s existence on Earth, he has been illiterate, unable to read and write. In order to survive, mankind needed to learn. By learning through sight and sound, along with tactile experience, mankind became the dominant species on Earth. Through the millennia our brains have been genetically reengineered time and time again to enhance our visual learning abilities.

Understanding text is a recent event in our evolutionary history. Although Britain was the leading world power 150 years ago, 35% of men, and 50% of women, in Britain, couldn’t read or write at that time. Even today 20% of World’s population is illiterate.

Text is good for the transfer of facts, like the length and weight of an object. However, it is much less effective in describing a visual experience. The short-comings of text are best described by the saying “*a picture is worth a thousand words*”.

Text is ineffective at creating an explicit common vision of an experience. Reading text requires imagination to fill in the blanks created by “text only descriptions” and the result is a difference in understanding between people. This difference in understanding leads to error and unwanted costs.

### **How important is the Troubleshooting Module in eliminating cost?**

Your text-based process SOP tells you what to do, but lacks the visualization delivery system to ensure that everyone understands. The UOVRST<sup>TM</sup> Trouble Shooting option provides a hierarchical structured set of questions to take you to the proper library clip so as to explicitly show the *how* and *why* for each SOP. For complex equipment systems, downtime can still be unacceptable unless employees have strategies and tactics for getting the system back up and running as soon as possible. Capturing the intellectual capital associated with troubleshooting the system in a logical and productive process is the key to ensuring that the process runs at maximum capacity.

Effective troubleshooting requires two skill sets. The first is knowing “*what and how*” to do something and the other is “*when*” to do it. Doing the wrong thing right won’t get the system up and running. Also doing the right thing wrong doesn’t fix the system. The intellectual capital or experience associated with “*when*” to do something can be captured in the optional Aries Troubleshooting Module.

The module is structured in a hierarchical interactive format. It is an option added to the Learning Module Interface and accesses the existing library.

### **Does Aries have any data where performance improved and human errors went down using the UOVRST<sup>TM</sup>?**

For errors based on misunderstanding to decrease, two factors must be addressed. The first is to provide a learning system that truly addresses the issue of learning styles, as the vast majority of technical personnel are visual learners (one of our other FAQ’s addresses this issue in more detail). The Unit Operation Visual Reference System<sup>TM</sup> was designed specifically to address *learning style*. The second factor is to ensure that the learning is actually implemented within the production environment, and that the Operations group takes on the ownership for the implementation. This means deliberate practice based on the learning materials provided within the Unit Operation Visual Reference Library. Our history has shown that only where there was an implementation issue, did error reduction or productivity gains fail to meet initial expectation. In those cases, through a variety of internal stimuli, the production units refocused, put the stake in the ground, and after assuming ownership, the error reduction and misunderstanding virtually disappeared. If an employee really understands, “*the what, the how, the why, along with the when*”, then the task is done correctly. It is through unconscious incompetence that 95% of employee error from misunderstanding occurs. There is no reason not expect a 90% plus decrease in error due to misunderstanding if our UOVRST<sup>TM</sup> process is fully implemented. As in the pharmaceutical business, for a drug to really affect the disease state, it has not only to

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be effective, but the patients must take the drug as directed. Similarly, UOVRST<sup>™</sup> is an effective learning tool and employees need to “use it as directed”.

**What makes Aries Communications the company of choice to partner with us in our learning process?**

Aries Communications was founded in 1996 and has provided technical media for Fortune 50 companies on three continents. Like any great innovation, it is a fusion of two enabled specialties; technical expertise and artistic creativity.

On the technical side, we have more than 120 years of collective pharmaceutical experience covering Quality, R&D, Operations, Regulatory, and Business Process Improvement. Our team has been granted 22 US patents, has taught at five major universities, and has won numerous international awards of excellence.

Our creative media team has also won numerous awards and has been cross-trained in the critical aspects of our technical business. Our Director of photography has more than 20 years of experience, and our principal Director has directed two multi-million dollar feature length movies (My Brother’s Keeper, The Marsh) along with many commercials and corporate features. Our creative staff has extensive university training in film, video, music, graphic design, and animation.

Aries does not need to sub-contract any media production work as we have our own state-of-the-art studio located in Markham Ontario. It is equipped with a film/video sound stage, which is located in the same building as our post-production facilities. We also specialize in case study Continuing Medical Education (CME) media for the Pharmaceutical Industry, and have provided dynamic video presentations for their sales meetings.

With expertise in innovation, we can provide a ½ day, or full day, workshop on innovation designed to enable and energize your organization. It is intended for groups of 5 to 30 to maximize the experience and learning. It is delivered at the client’s site.

**I have changed the content of an SOP that is associated with UOVRST<sup>™</sup> learning media. What are the costs and timing to update the UOVRST<sup>™</sup> media?**

As our client list has been growing, we've noticed that when one of our clients makes a change to a procedure that affects a UOVRST<sup>™</sup> library module, that we have provided, it very seldom requires additional cinematography changes. In greater than 95% of cases, the change needs only to be reflected in the narration or on-screen text effects. The vast majority of changes have required less than a minute of narration per change. Aries also recognizes that the cost and time to generate purchase orders for these changes can exceed the costs to cover the change itself. Therefore Aries will provide narration

updates for every UOVRST™ library module, provided to the client, at no additional cost. Our standard turn around time is 5 business days from receipt of the changes via e-mail.

When minor cinematographic changes are required, they are generally less than a minute in duration and are less than 3% of all changes made. In that situation, Aries uses hi-resolution single frame photography to construct the replacement video. This technique is excellent for small changes and is virtually indistinguishable from the original media when integrated back into the UOVRST™ library module. The digital photos to generate the new video media, can be provided by the client, if that options is required for timing reasons.

### **Our company has already implemented the Six Sigma system to improve our processes...why would we need UOVRST?**

The fundamental objective of the Six Sigma methodology is the implementation of a measurement-based strategy that focuses on process improvement and variation reduction through the application of Six Sigma improvement projects. The Six Sigma DMAIC process (Define, Measure, Analyze, Improve, Control) is an improvement system for existing processes falling below specification and looking for incremental improvement. All the work in Defining, Measuring and Analyzing process problems pays off in the implementation of the Improvement phase, which is where UOVRST™ can help you maximize the benefits of all of your project team's efforts. The current methods used to express *how people actually implement the Six Sigma improvements* are mostly text based, occasionally supplemented by some simple visuals. It is well known that most technical people are visual learners and learning is only maximized when learning style is addressed. The UOVRST™ approach ensures that employees really understand all of the subtleties of the improvement and can execute them as they are supposed to. If they don't understand, then subsequent measurement may infer that the process is not in control, when it is really the understanding that is not in control. UOVRST™ ensures consistent understanding of your best practice improvements. People carry out the majority of processes, and if they don't understand, then the improvements won't occur.

### **If our company is already implementing a quality improvement strategy such as 6 Sigma, BPR, TPS, Lean Manufacturing, or Kaizen, why would we need UOVRST™?**

Most major companies are involved in some form of improvement process most of which will affect a common underlying result and that is change. Key processes get improved and that means that they will be done differently. Employees now need to throw away the old ways and embrace the new process procedures. If the plan is to use text-based training aids to drive the change then all the effort spent in evaluating and analyzing the old process may end up wasted because employees don't have a clear understanding of the new process!

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Research has shown (refer to our White Paper on learning), that most technical people are visual learners. The term a picture is worth a thousand words could not be truer. In fact, misunderstanding generally translates in error and non-conformance costs. It is well documented that in order to maximize understanding one needs to receive information in the form that matches ones learning style.

Ultimately, in any improvement process, the improvement is implemented, but not everyone has the same understanding. There may be individuals who did not participate in the original improvement evaluation process and therefore do not have the same background to ensure complete understanding.

Following characterization of the improvement, UOVRST<sup>TM</sup> is used to capture the *HOW*, *WHY*, and *WHEN* details of the new process in a visual format that ensures complete understanding. UOVRST<sup>TM</sup> also makes possible the retention of the human intellectual capital in a format that retains all of the visual richness of the improved process so that the company can transfer the unadulterated meaning of the new process with the confidence that everyone will completely understand.

To realize the benefits of productivity improvement it is not sufficient just to technically improve a process; you must ensure that everyone involved fully understands. It is the successful implementation of the improvement that generates the productivity gain.

Implementing UOVRST<sup>TM</sup> to teach the improvement details will ensure that you will actually benefit from the all of the effort invested into the search for increased productivity.

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